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Colocation Still Matters: Conformance Quality and the Interdependence of R&D and Manufacturing in the Pharmaceutical Industry

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This study investigates the conformance quality benefits of colocating manufacturing with research and development (R&D) activities. Findings from a panel data set of U.S.-based pharmaceutical plants over a 13-year period reveal that colocation of manufacturing and R&D relates to better conformance quality, on average, across the entire sample. We find that these benefits of colocation persist throughout the time period we study (1994–2007), which is surprising, given the rapid development of information and communication technologies during that time. These benefits are particularly enhanced for manufacturing plants operating with processes that involve a high level of tacit process knowledge and that belong to large firms. Our findings highlight the importance of matching organizational design with process and firm characteristics in settings involving knowledge interdependence. They also highlight the continued value of physical proximity through geographical colocation between manufacturing and R&D activities to achieve desired quality outcomes.

Keywords: colocation; knowledge interdependence; organizational design; intraorganizational learning; quality management; pharmaceutical manufacturing; information technology
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1. Introduction

Should manufacturing activities occur in close proximity to research and development (R&D) activities? The question of whether colocation—i.e., reducing the physical distance between organizational units—can benefit manufacturing performance lies at the interface of the operations management and organizational design literatures. Expectations about the benefits of colocating R&D with manufacturing are contradictory. Pisano (1997, p. 11) observes that "[in] industries such as pharmaceuticals (...) both product and process technologies not only evolve rapidly, but also must be well synchronized." However, other research suggests that R&D and manufacturing represent distinct units with inherently different organizational and professional logics that may require structural and spatial separation (Jansen et al. 2009). In practice, R&D and manufacturing are often considered separate activities to the point that in many firms, manufacturing activities have been either removed from the firm's hierarchical organization (i.e., outsourced; Cockburn 2008) or removed from the firm's home country (i.e., offshored; Pisano and Shih 2009). Yet some U.S. manufacturers are again building manufacturing plants closer to their domestic R&D operations (Sirkin et al. 2012). A contributing factor to this may be a growing recognition of the knowledge interdependence of manufacturing and R&D (e.g., Fuchs and Kirchain 2010, Fuchs 2014). These observations point to the ongoing tension between viewing manufacturing and R&D as separable activities that should be dispersed geographically or as inseparable activities that require integration through colocation.

The seminal work of Allen (1977) has established that proximity among R&D team members contributes to positive gains for R&D performance. Van den Bulte and Moenaert (1998) also found evidence of greater interactions among R&D personnel when colocated, but they failed to establish that interactions between R&D and marketing personnel increase on colocation. It is thus unclear that colocation naturally leads to improved cross-functional problem solving and associated performance outcomes. This is particularly true in the context of R&D-manufacturing colocation and its effect on *manufacturing* performance. This relationship is the key focus of our study. Further, to account for contextual variations, we propose contingencies arising from the type of process involved and the size of the firm in question. These contingencies help explain why colocation may matter more in certain contexts than in others.

Our research question gains further importance when seen in light of the rapid advancements in information and communication technologies (ICTs)—and the diffusion of the Internet in particular. The diffusion of ICTs leads one to expect that any challenges associated with coordination and knowledge transfer across distance would have diminished over the last two decades. Eppinger and Chitkara (2006) asserted that "product design processes today are fully digital and completely networked. Computer design tools are the norm; high-bandwidth networks are ubiquitous," (p. 24) leading to the ability to spread product development networks globally. Evidence abounds that ICTs across commercial establishments in the United States have proliferated (Forman et al. 2002), thus reducing the time and costs of knowledge transfers and knowledge coordination across geographically dispersed teams (e.g., Cairncross 2001, Agrawal and Goldfarb 2008, Ding et al. 2010, Forman and van Zeebroeck 2012) and enabling new organizational designs that reflect these changes in the external environment (e.g., Van de Ven et al. 2013, Kim et al. 2009). The benefits of colocation for product development outcomes were empirically established at a time when the Internet had not diffused broadly (e.g., Clark and Fujimoto 1991, Adler 1995). Our study examines if the benefits of colocation have persisted despite this massive technological change in terms of the diffusion of ICTs.

Our analysis of a panel data set of U.S.-based pharmaceutical manufacturing plants observed over the period 1994–2007 shows that, on average, plants colocated with R&D units tend to have a better record of conformance quality than noncolocated plants, as assessed by the U.S. Food and Drug Administration's (FDA) plant inspections. The observed probability of obtaining an adverse inspection outcome (i.e., in which the FDA issues an official action as a result of the inspection) in our data is reduced for colocated plants (16% probability[1]) relative to noncolocated plants (20% probability). To put these results in perspective, this effect of colocation on conformance quality is approximately equivalent to a plant belonging to a firm that is 1.4 standard deviations above average in terms of capital intensity (i.e., much more automated than normal). As evidence of the economic importance of these results, recent research shows that an adverse inspection outcome is associated with a 37% increased hazard of having a Class 1 or Class 2 recall over the succeeding 1.5 years (Ball et al. 2015). Although reliable data on the average costs of such recalls are unavailable, anecdotal evidence suggests that some Class 1 manufacturing-related recalls can lead to measurable costs of close to $1 billion (Nussbaum 2011).

We examine three moderators of the benefits of colocation. Surprisingly, we find that the benefits of colocation persist across time and across plants with greater access to ICTs. This result indicates that colocation still matters; i.e., the "death of distance" (Cairncross 2001) ushered in by ICTs has not negated the value of face-to-face communication in our context. Consistent with our expectations, we also find that plants whose products are associated with higher levels of tacit knowledge in their manufacturing process (e.g., biotech, vaccines, or sterile liquids) benefit more from colocation than those plants with more codified production processes. For plants involving processes with high levels of tacit production knowledge, colocation relates to a reduction of eight percentage points (from a 22% probability to a 14% probability) of an adverse inspection outcome. The third moderator we examine is firm size. For plants owned by larger firms, colocation again relates to an eight percentage point reduction (from a 20% to 12%) of an adverse inspection outcome.[2]

To add richness to our data analysis, we also interviewed several executives with experience in pharmaceutical manufacturing. Those executives who were familiar with both colocated and noncolocated sites expressed near-universal agreement that colocation is beneficial to conformance quality. The reasons they give pertained to improved knowledge flows and included the following: (1) colocation gives R&D a "GMP[3] mindset," resulting in designs more suitable for manufacturing with consistent conformance quality; (2) technology transfer efforts that are shared instead of being "handed off in one direction,'' with "R&D's rationale for process control parameters and in-process control tests" also shared, resulting in better ramp-up; and (3) R&D being "more than happy to get involved" in troubleshooting issues during ongoing production, resulting in "better operator awareness and understanding."

[1] All probabilities expressed in this introduction refer to simple observed percentages in our data. See the analysis section of the paper for model specific estimated probabilities.

[2] These two contingencies are strong enough that our analysis reveals some evidence that colocation may actually be detrimental to plants of smaller firms with a nontacit (i.e., codifiable) production process. However, it is important to note that this effect is not robust to sample and method.

[3] GMP refers to good manufacturing practices, outlined in the Code of Federal Regulations (21 CFR, parts 210 and 211). GMPs are "a set of practices and behaviors that, when a plant complies with them, should lead to a low likelihood of defective product being shipped from a manufacturing facility" (Gray et al. 2011, p. 743).

Our research makes four contributions to the literature. First, we test the central hypothesis on the effects of colocation in a large-scale archival data set with almost 1,000 plants belonging to more than 500 firms. Previous tests of the benefits of colocation have used a smaller-scale survey or indepth case data sets, such as the seminal studies of Clark and Fujimoto (1991; 17 firms), Adler (1995; 10 firms), Ettlie (1995; 43 firms), and Datar et al. (1997; 3 firms). Testing for the benefits of colocation across a wider set of firms with archival data is a necessary exercise of replication. Second, much of the existing empirical work is based on data sets that were collected in the early 1990s—a time during which ICTs mattered much less than in subsequent years. Thus, revisiting whether the benefits of colocation still matter for knowledge flow is an important research objective. Third, beyond simply observing the occurrence of planned interaction and communication (e.g., Van den Bulte and Moenaert 1998) between manufacturing and R&D units, we examine colocation's relationship to a key operational metric, manufacturing conformance quality. Previous work has mostly focused on outcome metrics associated with product development, such as time to market (Datar et al. 1997) or innovation measured by patents (Fifarek et al. 2008). Fourth, we examine firm- and process-level contingencies to isolate the conditions under which the benefits of colocating R&D and manufacturing may exceed the drawbacks of such an organizational design. In particular, we draw on prior research that recognizes that certain manufacturing processes embody more tacit knowledge (e.g., Bohn 2005, Fuchs and Kirchain 2010) and may therefore benefit more from proximity to R&D. Further, large firms possess superior organizational and managerial capabilities (Bloom et al. 2013), and our results imply that they employ these capabilities to enhance the benefit of a colocated organizational design. These contingencies help us establish that under some conditions, colocation matters less or not at all.

2. Hypotheses

2.1. R&D–Manufacturing Colocation and Conformance Quality

Our outcome variable of interest, manufacturing conformance quality, is the relative tendency of a manufacturing plant to operate its processes in compliance with established quality-related procedures. Operating with high levels of process compliance increases the likelihood that products are shipped from the plant without defects. Colocation—our key independent variable of interest—is an indicator of whether a manufacturing plant's firm also has R&D activities located in the same physically proximate geographic location.

It is well established that R&D and manufacturing are interdependent activities. As Dean and Susman (1989, p. 28), note, "nowhere in a firm is the need for coordination more acute than between the people who are responsible for product development and those responsible for manufacturing." A key premise of the design-for-manufacturability literature (e.g., Ettlie and Stoll 1990, Adler 1995) is that the design of a product has an effect on its manufacturability. More directly focused on quality is the related concept of quality by design (Juran 1992, Yu 2008). Many empirical studies in quality management measure some aspect of designing products for manufacturing quality as a key part of a quality program (e.g., Flynn et al. 1995, Kaynak 2003). In Nair's (2006) meta-analysis of this literature, constructs related to product design were positively correlated with operational performance.

Prior studies have argued that interdependent activities—i.e., activities that require close coordination of knowledge and decision making—should benefit from an organizational design that enables such coordination between them (e.g., Thompson 1967, Pennings 1975, Van de Ven et al. 1976, Galbraith 1977). In the absence of face-to-face interaction, which is the richest form of communication (Daft and Lengel 1986) and "the most direct and easy route to cooperation and coordination" (Kiesler and Cummings 2002, p. 64), firms may incur substantial costs in coordinating and integrating the knowledge residing at dislocated sites (von Hippel 1994, Pisano 1997). Drawing attention to the importance of location for collaborative activities, Tyre and von Hippel (1997, p. 73) argue that physical proximity is an important aspect of collaborative processes and joint problem-solving activities because "where activities take place partly determines what actors can do, what they know, and what they can learn." Relatedly, teams that are physically dispersed are more likely to experience less communication among team members (Allen 1977, Sosa et al. 2002, Van den Bulte and Moenaert 1998) and less access to each other's knowledge (Staats 2012). By providing a common technological *and* organizational platform, colocation allows for frequent interaction and knowledge flows (Thompson 1967, Van de Ven et al. 1976).

Building on this prior literature, we suggest that integration of R&D and manufacturing through colocation can improve conformance quality at the manufacturing plant. We view the process that brings a product to market as a problem-solving continuum, where the locus of problem solving shifts from R&D to manufacturing through three distinct phases: product development, ramp-up, and ongoing production.

In the product development phase, the fact that R&D personnel can see the current manufacturing operation and talk to manufacturing personnel increases the likelihood that the process will be designed for manufacturability (Ettlie and Stoll 1990). R&D personnel can also enable learning during manufacturing ramp-up. As noted by Bohn and Terwiesch (1999, p. 47), "the key driving force behind ramp-up is usually learning of various kinds." The challenge of managing this learning process across distance at ramp-up is highlighted by a recent study of product launches in the automotive industry, which shows that plants learn from their own experience but learn little from the experience of other plants (Gopal et al. 2013). During ongoing production, R&D knowledge can be important for troubleshooting the problems that inevitably arise; colocation will make this knowledge more accessible to manufacturing and also likely increase R&D personnel's level of ownership for manufacturing performance. An executive with years of broad experience in pharmaceutical manufacturing provided the following insight about the advantages of colocated sites:

> While at [company X, in R&D], I worked at a site that had colocated R&D and manufacturing. I participated in joint meetings with quality, manufacturing and colleagues on quality/manufacturing issues. This did not happen routinely for distant sites that I interacted with unless the issues were substantive enough that I went to the plant. I believe these meetings always resulted in good decisions being made based on all information from all perspectives.

We therefore present the following central hypothesis:

Hypothesis 1 (H1). *Manufacturing plants colocated with R&D operate at a higher level of conformance quality than noncolocated plants.*

Hypothesis 1 presents the first-order effect of colocation on manufacturing quality. The next set of hypotheses examine three contingencies affecting this relationship: access to ICTs, the level of tacit process knowledge required to produce the plant's products, and firm size.

2.2. Moderators of the Effect of Colocation on Conformance Quality

2.2.1. The Contingent Effect of Information and Communication Technologies. Hypothesis 1 is based on the idea that the interdependence of R&D and manufacturing units requires the transfer and synthesis of specialized and sometimes tacit knowledge, which can be difficult to achieve across geographical distance (Teece 1977, Szulanski 1996). ICTs can benefit all organizations, including geographically proximate ones, by enhancing existing communication mechanisms, such as face-to-face interactions for knowledge coordination (Agrawal and Goldfarb 2008). We assert that although ICTs can benefit both colocated and noncolocated manufacturing units, improvements in knowledge coordination and knowledge transfer across manufacturing and R&D are likely to be the greatest for noncolocated plants. This is because "communication technologies ... seem to offer a substitute for face-to-face communication" (Kiesler and Cummings 2002, p. 67). For example, recent studies have pointed out that access to even the most basic ICTs—such as email, common access databases, videoconferencing, and file sharing software—can significantly mitigate these distance-related impediments to collaboration, coordination, and knowledge transfer, both within (Argyres 1999, Forman and van Zeebroeck 2012) and across organizations (Agrawal and Goldfarb 2008, Ding et al. 2010). Attesting to this effect, one expert we interviewed noted, "Skype is very helpful in communicating. The ease with which video and pictures can document issues is also extremely helpful." Furthermore, ICTs may create common social and technical platforms that make it less costly and more efficient to engage across geographical distance (Argyres 1999). Since ICTs serve to partially substitute for face-to-face interactions, the gains from ICTs in terms of conformance quality will be greater for noncolocated plants than for colocated plants, where face-to-face interaction is available.

Hypothesis 2 (H2). *The conformance quality advantage of manufacturing plants colocated with R&D is reduced when plants have greater access to ICTs.*

2.2.2. The Contingent Effect of Tacit Process Knowledge. Fundamental to H1 is the notion that a nontrivial level of interaction between R&D and manufacturing units is required to achieve high levels of conformance quality. The extent to which interaction between organizational units such as R&D and manufacturing is beneficial will not be equal across all firms (Lawrence and Lorsch 1967, Thompson 1967, Van de Ven et al. 1976) and may vary according to the types of manufacturing processes. As Nickerson and Zenger (2004) articulate, the required interdependence of two knowledge sources depends on the nature of the problem the two sources must coordinate to solve. Thus, the extent to which colocation improves conformance quality will vary according to the manufacturing process. Plants with processes that use more tacit knowledge are those for which the exact steps to achieve and maintain high levels of conformance quality are not precisely known; i.e., the means-ends connections are inexact (Tyre and von Hippel 1997). Bohn (2005) describes such processes as "embryonic technology or art," characterized by tacit knowledge and idiosyncratic outcomes. Examples of such processes include cutting-edge semiconductor manufacturing (Macher 2006) and biotechnology manufacturing (Pisano 1994). This is compared to processes that are "ideal technology or science" and hence more codified (Bohn 2005). Examples of such products include a part machined from a standard raw material or a plastic product made using standard materials and injection processes. These have more codified production processes, wherein R&D can "throw the blueprint over the wall" and expect high-quality production.

For processes with high levels of tacit knowledge, colocation with the R&D unit becomes more advantageous for two main reasons. First, tacit knowledge (e.g., Polanyi 1966, Nonaka and von Krogh 2009) is more difficult to transfer across distance (Szulanski 1996) than codified knowledge. Since codified knowledge can be readily transferred, the benefits of colocation are diminished. Second, a high level of tacit process knowledge relates to a greater tendency for situations to arise wherein written procedures either do not exist or need to change. Such situations benefit from R&D. For example, as Fuchs and Kirchain (2010, p. 2325) note, "in certain contexts—particularly, unfamiliar, unstructured problems—problem solving requires experts being physically present to recognize embedded clues, exploit specialized tools, and find and interpret relevant information (Tyre and von Hippel 1997)." In another study, Terwiesch and Bohn (2001, p. 1) similarly observe that production ramp-up of "poorly understood" processes can be accelerated by putting in place approaches for "deliberate learning through … controlled experiments using the production process as laboratory." We suggest that such experimentation and trials may be more necessary in the context of tacit production knowledge, which can benefit from face-to-face interaction between manufacturing and R&D.

Hypothesis 3 (H3). *The conformance quality advantage of manufacturing plants colocated with R&D is enhanced when the plant's production process involves more tacit knowledge.*

2.2.3. The Contingent Effect of Firm Size. Another important contingency that could moderate the benefits of colocation pertains to the size of the firm. Whereas firm size is related to many different organizational aspects, our hypothesis draws on the established result that larger firms typically "have more structured management practices" (Bloom et al. 2013, p. 12) and that the level of these structured management practices correlates well with indicators of management effectiveness (Bloom et al. 2013). Deciphering the underlying causes of such effectiveness is unnecessary for our hypothesis development, but it is likely that scale-driven managerial effectiveness occurs partially because only effectively managed firms are able to grow. Also, as firms grow, existing managers gain experience dealing with increased organizational complexity. Furthermore, growing firms tend to replace or complement the founding managers with managers that have expertise dealing with more organizationally challenging situations (Hambrick and Crozier 1985). As Henderson and Cockburn (1996, p. 33) observed, "the primary advantage of large firms appears to be their ability to realize returns to scope: … to capture and use internal and external spillovers of knowledge." These characteristics of large firms, however, lead to competing predictions concerning the benefits of colocation.

The arguments leading to the formation of H1 focused on the challenges of managing interdependent activities and coordinating knowledge across distance. However, as Van den Bulte and Moenaert (1998) found, increased physical distance "did not result in lower levels of communication" (p. S15) between R&D and other functions, because of "substantial efforts to develop procedures conducive to an innovative climate throughout the company" (p. S15). The conclusion from this finding is not that colocation does not enhance communication, but rather that "organizational procedures and systems can compensate for some of the negative aspects traditionally associated with locating some units apart from the rest of the organization" (p. S15). Consequently, one might infer that larger firms are likely better equipped with the organizational and managerial capabilities to establish systems for planned interactions and coordination across distance. By necessity, firms that have grown in size have developed organizational routines and processes to manage the challenges of knowledge coordination across disparate or geographically dispersed organizational units (Gittell 2002). Smaller firms, on the other hand, may need colocation to coordinate interdependent activities due to a lack of structured organizational processes for knowledge exchanges across distal units.

As one of our interviewed experts put it, "Some small companies (1) think that processes slow down progress, (2) think that processes are too expensive to implement, or (3) may not have the expertise or experience to understand and/or implement best practices…. Companies without formal processes rely on serendipitous discussions that happen in hallways or at the lunch table, both of which rely on colocation." These arguments lead to the following hypothesis:

Hypothesis 4A (H4A). *The conformance quality advantage of manufacturing plants colocated with R&D is reduced when the plant belongs to a larger firm.*

Previous literature also provides evidence that managing a colocated site is often quite challenging for managers. For example, Clark and Fujimoto (1991, p. 168) observe that "the essence of effective production management is stability, efficiency, discipline and tight control, whereas effective R&D management requires dynamism, flexibility, creativity, and loose control." At least on the surface, R&D and manufacturing represent very different organizational logics or sets of principles governing organizational actions (Friedland and Alford 1991). Organizational theorists have observed that such different and potentially contradictory organizational logics create the potential for organizational conflict (e.g., Marquis and Lounsbury 2007, Greenwood et al. 2011) and can detract from learning due to cognitive constraints (Vasudeva et al. 2015). When R&D and manufacturing are colocated, such conflicts can hamper knowledge integration. As Huckman (2009) details, achieving separation between diverging organizational units becomes necessary to establish clear objectives for the different units, set boundaries between the units that are not too broad or too narrow, and actively manage the interactions between these units. Our interviews also revealed an understanding of the managerial challenges in achieving the benefits of colocation, indicating, for example, that a "collaboration mindset" was necessary and that achieving the benefits "hinges on the plant's ability to distinguish between issues which necessitate R&D assistance and those which don't." Clearly, these are subtle challenges that require a good deal of organizational and managerial skills to overcome. Given that larger firms are more likely to possess the specialized management skills and resources to successfully cope with the challenges of R&D and manufacturing colocation, we propose the following:

Hypothesis 4B (H4B). *The conformance quality advantage of manufacturing plants colocated with R&D is enhanced when the plant belongs to a larger firm.*

3. Empirical Setting

Our empirical setting is U.S.-based manufacturing facilities that are considered "drug manufacturers" by the FDA. This setting has several characteristics that are conducive to our study. First, conformance quality is important in this industry. Failure to operate under high levels of conformance quality is illegal, can result in significant risks to human health, and can affect firms directly through product recalls and potential plant closures. Second, the industry is R&D intensive, and the process technology is sufficiently tacit so as to possibly benefit from some level of manufacturing–R&D interaction. Third, there is substantial variance of colocation strategies across the industry. Fourth, the FDA provides periodic assessments of a plant's process compliance through regulatory inspections; the outcomes of such assessments serve as evidence of whether a plant is operating in compliance with regulations designed to ensure a high level of conformance quality. Finally, within the industry, there is substantial variation in the penetration of ICTs, firm size and the level of tacit process knowledge, all of which are at least coarsely detectable using secondary data. This variation allows us to assess these moderating effects based on our theoretical predictions.

3.1. Data Sources and Measures

In this section, we present both the source and specific measures for all variables used in the study. To perform this research, we combined several secondary data sources. For reference, we list each data source and the variables obtained from the source in Table 1.

3.1.1. Dependent Variable. The frame for our analysis is the population of all sites inspected through the FDA's Establishment Inspection Program. This includes all inspections of manufacturing sites that produce pharmaceutical products that are sold in the U.S. market. The original database of inspection outcomes from January 1994 to January 2007, which was obtained by a Freedom of Information Act request, included nearly 30,000 inspections from more than 14,000 sites. We excluded all sites with fewer than three inspections. This restriction was made mostly for data-analysis-related reasons, since we required a previous inspection outcome to estimate our main model and desired multiple observations per site. We removed all inspections that took place in nonmanufacturing plant sites, such as individual doctor practices, fire departments, hospitals, and blood banks. We further removed all plants whose firm name could not be found in the ORBIS database from which we obtained some firm-level control variables. This likely excluded many small private firms from our analysis. Next, we excluded all non-U.S. plants, primarily to enable collection of additional firm data from sources only available in the United States After these deletions, we had data on 8,832 inspection outcomes at 1,238 manufacturing plants from 804 different firms. This is our core sample, but since different analyses throughout our paper depend on different additional control variables with varying degrees of missing data, the actual samples used in our analyses are smaller.

Our dependent variable is operationalized using the FDA's assessment of compliance with GMPs. GMPs are outlined in the Code of Federal Regulations (21 CFR, parts 210 and 211). By design, a plant operating under high levels of compliance with GMPs should have a low likelihood of shipping a defective product, an assertion that was confirmed by a

Table 1 Data Sources

Variable type	Source	Variable(s)
Dependent	FDA establishment inspection database	Conformance quality (*inspection outcome*)
Hypothesized	Thomson Innovation patent database	*Colocated* (H1–H4A and H4B) (based on patent assignee city)
	National Establishment Time Series database	*Colocated* (H1–H4A and H4B) (based on plant SIC codes)
	Harte-Hanks	ICT Availability (*high bandwidth*) (H2)
	FDA establishment inspection database	ICT availability (*early*; inspection occurred before the year 2000) (H2)
	FDA plant-level data; coded by expert panel	Tacit process knowledge (*tacit processes*) (H3)
	COMPUSTAT (Wharton Research Data Services)	Firm size (*large firm*) (H4A and H4B)
	ORBIS database, other sources	Firm size (*large firm*) (H4A and H4B); robustness check for private firms[a]
Control	FDA establishment inspection database	Inspection year (*year*), *previous inspection adverse*, *time since last inspection*, inspection type (*surveillance, consumer complaint, compliance*), *inspection frequency*, *cluster* (based on plant location), *number of plants*
	National Establishment Time Series database	Plant type (*headquarter*, *branch*, *standalone*), *credit score*, *plant age*[a]
	Census	*Population density* (of zip code tabulation area whose centroid is nearest the plant location)
	National Historical Geographical Information System	*Wage rate*
	COMPUSTAT	*R&D intensity, capital intensity, Tobin's Q*
Linking firms to plants	Thomson, ORBIS, and Google	Identification of firm that owns the plant[b]
Instruments	National Establishment Time Series database	*Plant size*[a]
	National Historical Geographical Information System	*Labor pool* (available labor pool at the plant city in three separate employment categories)

[a]For these variables, the data were supplemented with directed Internet search to check accuracy and fill in missing data.
[b]Some ownership changes were evident from the FDA inspection data.

panel of industry experts (Gray et al. 2011). We call operating under high levels of compliance conformance quality. We note that FDA inspection data have been used in previous studies to study different research questions. Inspection-level outcomes have been labeled "process [non]compliance" (Anand et al. 2012, Gray and Massimino 2014, Gray et al. 2015), and an aggregated plant-level measure was labeled "quality risk," which was defined as a "propensity ... to fail to comply with good manufacturing practices" (Gray et al. 2011, p. 738). This propensity to comply is a key driver of conformance quality, the term we adopt in this paper. The FDA's assessment of process compliance is recorded as follows: After each inspection, the FDA inspector sends an Establishment Inspection Report to the district; this report may or may not contain a Form 483. This form documents objectionable conditions observed by the inspector. The district reviews this report, considers other possibly relevant plant-level data (e.g., consumer complaints, test sample results), and classifies the inspection outcome. We record an adverse inspection outcome if the district records "official action." Such an outcome indicates that the district believes that the compliance issues are severe enough to require a written response from the firm. Official action classifications are almost always accompanied by a warning letter, which the FDA makes public on its website. For the plants in our core sample, 18% of all inspections resulted in an official action. The FDA lists the top reasons for citations on its website.[4] The most common violations relate to the lack of or failure to follow procedures related to production or laboratory operations. Others relate to failure to fully investigate problems; failure to train employees; and issues related to cleaning, maintenance, or calibration of equipment. Clearly, plants operating with such deficiencies would have a greater propensity to ship defective products.

Because of the complex nature of our analysis, we coded *inspection outcome* as 1 if an adverse outcome (official action) was observed and 0 otherwise. We did not consider other outcomes, such as a voluntary action decision by the district or whether a Form 483 was issued by an inspector. Regarding voluntary action, a panel of experts familiar with FDA inspections indicated that a voluntary action outcome represented much less information about the level of compliance than an official action outcome did (Gray et al. 2011). Similarly, current research about the relationship between these inspection outcomes and future recalls reveals a significant increase in the hazard of a recall if official action outcomes are observed, but only little such increase is observed for voluntary action outcomes (Ball et al. 2015). Regarding Form 483, this outcome (yes/no) is highly correlated with the district decision and thus provides little additional information.

[4] http://www.fda.gov/ICECI/EnforcementActions/ucm326984.htm (accessed May 30, 2014).

3.1.2. Independent Variable. We used multiple data sources for our main independent variable (i.e., colocated). First, we used the Thomson Innovation database to search for patents generated in each plant location in our data set. In the absence of detailed R&D data, patents serve as a well-established indicator of firms' inventive activity (Griliches 1990). After downloading all patents for all firms for which we had inspection data, we searched for patents in which the assignee firm's city was the same as the city of the plant location. We found that 229 plants (19%) had a patent on record in the same city during the time period captured in our data set (1994–2007) or up to five years prior. However, some of this patenting activity may reflect exceptional engineering groups producing process- (not product-) related patents. We therefore manually classified the patents assigned to each plant's location as product or process related. We standardized coding instructions to identify the process patents until adequate interrater reliability was achieved among a test set of patents. For plants with a large number of patents, a random sample of 100 patents was recorded instead of the whole set. A resulting 31 of the 229 colocated plants had only process-related patents and were therefore not coded as colocated. The later-reported results remain robust if these additional plants are coded as colocated instead.

Not all research activities in a plant lead to a patent assigned to that plant. Some research may not be patentable, and some research may lead to patents being assigned to other locations. To capture some of the plants with R&D capabilities that do not patent, we examined the SIC classifications of these plants as reported in the National Establishment Time Series (NETS) database. Plants with one of their SIC codes listed as 8731 (Commercial Physical and Biological Research) were considered to be colocated. Such classifications are voluntary and therefore imperfect. Nevertheless, 103 plants met this criterion for being considered colocated. Finally, since our patent classification as well as our theory emphasizes physical proximity, we identified all plants that were within 50 miles of a location that showed product patent activity within a firm's intraorganizational network. This criterion is intended to capture plants located within the same larger metropolitan area as an R&D facility. One hundred four plants met this criterion. In summary, for our main analysis, we classify a plant as *colocated* if it meets any of three criteria: (1) a product patent generated by the firm in the same city as the plant, (2) a SIC code from the NETS database indicating R&D activity, or (3) the presence of patent-generating activity by the plant's firm occurring within 50 miles of the plant. This led to a total of 335 of the plants in our data set being classified as colocated.

Note that criteria (1) and (2) do not lend themselves to a longitudinal differentiation of plants changing categories, since these measures are not frequently updated. Criterion (3), however, made the identification of a few plants possible, where the colocation status changed during our time frame through mergers or acquisitions. Although such an event is rare, occurring only in 9 of our 335 colocated plants, we kept this variance as the only within-plant variance in colocation.

3.1.3. Moderating Variables. Our analysis requires us to measure three moderating variables: access to ICTs, the level of tacit knowledge in the process at the plant, and firm size. We record all these variables in a dichotomous fashion, since such a discrete coding facilitates our analysis and the interpretation of our results by not requiring us to specify a functional form for the underlying interaction. A section in our analysis will examine a more fine-grained categorization of these constructs.

We employ the date of an inspection as one measure of ICT penetration. Since our data set spans the years 1994–2007, this time period roughly corresponds to the time during which the Internet gained wider adoption in business settings. We created a dichotomized variable, *early*, which is coded 1 for inspections before the year 2000 and 0 otherwise. Beyond this, we also explicitly measure the available ICT infrastructure at the firm. In particular, we obtain data from Harte-Hanks Market Intelligence, a market research firm, on the level of bandwidth available to the firms in our sample. As noted in prior studies (Forman and van Zeebroeck 2012, Forman et al. 2005), this data set represents the best source of data on ICT investments made by firms, and has been used to examine ICT adoption (e.g., Bresnahan and Greenstein 1996), decentralized decision making (e.g., Bloom et al. 2014), and the scope and performance of firms' activities (Ray et al. 2013). Although we did obtain plant-specific data on Internet bandwidth, we were only able to match about 100 of our plants to the Harte-Hanks database this way. However, the Harte-Hanks data allowed for a more comprehensive coverage at the firm level, enabling us to match 514 of our plants to firm-level Internet bandwidth. In particular, we summed up all recorded data lines at the firm level based on their corresponding bandwidth (T3, T1, xDSL, ISDN, and dial-up) and divided that number by the number of sites recorded for that firm to obtain a firm-specific measure of Internet bandwidth. Note that we used the most recent data as a measure for all years, since unfortunately the number of T3 lines measuring bandwidth was not recorded at the firm level for earlier years in our data, making a longitudinal assessment difficult. However, on assessing this measure at the site level, we did not observe major increases in bandwidth in the period 2001–2008 in the Harte-Hanks database. Thus, ICT penetration is measured at the firm level without within-plant variation. Using this measure, we classified all plants with a firm bandwidth per site greater than 10 megabits per second as *high bandwidth* (about the highest quartile of our data) and all sites with less than this benchmark as *low bandwidth*.

To code the level of tacit process knowledge, we obtained time-invariant product profiles for 729 of the plants in the database from the FDA. Specifically, the FDA categorized the products in each plant as belonging to one or more of 77 different categories, such as biological products, vaccines, and prompt-release tablets. We then recruited a panel of three experts, all of whom had extensive experience with pharmaceutical manufacturing, to independently rate these 77 profiles according to their level of tacit process knowledge on a 7-point scale, with 1 being the least and 7 being the highest. Specifically, the experts were asked to provide a single number that assessed both the level in the production process of knowledge which cannot be codified or written down and the level of instability of the process (i.e., the tendency for situations to arise wherein written procedures either do not exist or need to change). The experts' ratings were highly correlated with each other (average bivariate Pearson correlation $= 0.48$, smallest bivariate correlation $= 0.41$, all bivariate correlations significant [$p < 0.01$]), indicating high levels of interrater consistency. If we treat the experts as items and each product profile as an observation, we obtain a Cronbach's alpha score of 0.75, another indication that the experts were reliable. Given this, we averaged the three ratings from each respondent for each profile to create a score for the level of tacit process knowledge for each of the 77 FDA profiles. To create this score for a plant, we used the maximum of these ratings across all categories for a plant. We used the maximum since it was most closely related to our theoretical concept. The average would have meant that plants with one high tacit-knowledge category and one low tacit-knowledge category would have been coded as having less tacit knowledge than a plant with only a high tacit-knowledge category. In addition to the 77 product profile codes obtained from the FDA, there were five industry codes also assigned to the plants. We also had the experts code these industry codes on the same seven-point scale. In our data, 160 plants did not have any product classifications assigned to them but did have industry classifications available. For such plants, for our main analysis we used the experts' assessment of the level of tacit process knowledge for the assigned industry code. We classified all these plants with a tacit process knowledge score of greater than 5 on the 1–7 scale (20% of plants) as having a *tactic process*. Our main reason for choosing this cutoff was because the most general industry classification, human and animal drugs, was set at 5 by the panel of experts. Products such as vaccines, steriles, aerosols, parenteral and biologics rated greater than 5.

Firm-size data were obtained primarily from COMPUSTAT via Wharton Research Data Services.[5] We measure firm size by the total number of employees for the firm owning the plant in the year of the inspection. We create a dichotomous variable, *large firm*, which is coded as 1 for plants with more than 20,000 employees (42% of plants) and 0 otherwise. Forty-six plants changed their classification during the course of our study. All other plants were stable in their classification throughout our timeframe. In our sensitivity analysis, we use firm sales as an alternative measure of firm size.

3.1.4. Control Variables. We have data at the inspection level, which is our unit of observation, but our unit of analysis is the plant. Our analysis therefore contains three levels: (1) inspections, which are observed for a (2) plant, which in turn belongs to a (3) firm. We use control variables at all three levels. Note that for all control variables that are distinctively nonnormal in their distribution, we use the natural log transform of the variable in our analysis.

At the inspection level, we control for the outcome of the previous inspection. Furthermore, we use control dummies to classify inspections as *consumer complaint*, *compliance*, and *surveillance*. We also control for the natural log of days since the last inspection to capture the tendency of plants to move to a state of higher entropy in the absence of an inspection (Anand et al. 2012). Finally, we include fixed effects capturing the year of the inspection. These inspection-level controls were used in previous FDA inspection-level research (Gray and Massimino 2014, Anand et al. 2012, Macher et al. 2011). All are obtained directly from the FDA inspection data set.

At the plant level, we measure several factors. *Inspection frequency* is the number of inspections recorded in our data set divided by the number of years the plant appears in our data set. This measure correlates with the variety of product categories in a plant for those plants for which we obtained such data

[5] Note that our main analysis is performed only with public firms, partially because of the necessity of obtaining reliable longitudinal firm-size data. Firm-size data for private firms were obtained by manually searching the ORBIS database and other sources. These data were only used for a robustness test.

from the FDA ($r = 0.50$, $p \leq 0.01$), making it a reasonable and fully available proxy for the scope of a plant. Whether or not a plant was in a cluster was determined by examining the geographical density of the plants from the FDA inspection database. All locations were geocoded (i.e., mapped to a latitude and longitude). We used a geospatial plot of the data to confirm the existence of one large manufacturing cluster in our data set, located in an area that includes parts of Pennsylvania, New York, and New Jersey, around the latitude of 40.4 and the longitude of −74.7. This pharmaceutical cluster has been mentioned in previous research (Porter 1998). We created the variable *cluster*, coded as 1 for the 290 plants belonging to this cluster and 0 otherwise. The plant types are headquarters (186 plants), branch (266 plants), or standalone (290 plants), which we capture using two dummy variables for *headquarters* and *standalone*. This variable was taken without modification from the NETS database for each plant. *Population density* was measured for each plant's zip code using census data.

There are two plant-level control variables that, because of their high degree of missing values, we do not use in our main model. In particular, we measure plant age and a plant's credit score, both obtained from the NETS database. Since there was much missing data in NETS with respect to plant age, additional data on this variable were collected through extensive Google and LexisNexis searches. *Plant age* is measured as of 2007 (i.e., the last year in our study). *Credit score* is measured as the plant's minimum PAYDEX score in a year. The PAYDEX score captures whether plants pay their suppliers on time and relates to the financial health of the plant.

At the firm level, we control for four potentially relevant variables: *R&D intensity*, *capital intensity*, *Tobin's Q*, and the *number of plants* for that firm in our database. The first three of these variables were obtained from the Wharton Research Data Services database; the last originated from the FDA inspection data set. *R&D intensity* was measured as the firm's ratio of R&D expenses to sales. *Capital intensity* was measured as the ratio of total assets to total employees; it captures how much the firm relies on physical versus human assets in its production process. *Tobin's Q*, which has been used to capture a number of firm characteristics, including firm value and managerial performance, was measured by the method described in Chung and Pruitt (1994). Observations where the *R&D intensity* was higher than 2 or *Tobin's Q* was greater than 10 were recorded as 2 or 10, respectively. These restrictions affected less than 1% of available data. Table 2 provides summary statistics (at the inspection level, since that is our main unit of observation) for key plant- and firm-level variables used in the analysis.

Table 2 Descriptive Statistics

	Type	Level	Avg	SD	[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]	[9]	[10]	[11]	[12]	[13]	[14]	[15]	[16]
[1] *Insp. outcome*	D	I	0.18	0.39	—															
[2] *Colocated*	D	P	0.27	0.44	−0.11*	—														
[3] *Tacit process*	D	P	0.20	0.40	0.01	0.31*	—													
[4] *Large firm*	D	F	0.42	0.49	0.04	0.11	0.15	—												
[5] *High bandw.*	D	F	0.27	0.45	0.06*	0.02	0.09	0.61*	—											
[6] ln(*Insp. freq.*)	C	P	0.63	0.28	0.11*	0.21*	0.34*	0.04	0.15*	—										
[7] *Cluster*	D	P	0.23	0.42	0.02	0.13†	−0.07	0.07	−0.02	0.18*	—									
[8] *Headquarters*	D	P	0.25	0.43	−0.08*	0.44*	−0.04	−0.34*	−0.12	0.10*	0.04	—								
[9] *Standalone*	D	P	0.39	0.49	0.18*	−0.28*	−0.25*	−0.05	0.00	−0.06	−0.04	—	—							
[10] ln(*Pop dens.*)	C	P	7.23	1.43	0.10*	0.06	0.05	−0.02	0.06	0.16*	0.34*	0.06	0.11†	—						
[11] ln(*Plant age*)	C	P	2.97	1.13	−0.07*	0.06	−0.05	0.19*	0.07	−0.08*	0.00	0.06	−0.19*	0.01	—					
[12] *Credit score*	C	P	69.9	6.17	−0.02	0.05	−0.03	−0.15†	0.13	−0.04†	−0.01	−0.08	0.11†	−0.02	0.06*	—				
[13] ln(*Wage*)	C	P	10.9	0.16	−0.08*	0.12*	−0.11*	−0.26*	−0.10	−0.04†	0.72*	0.07	0.00	0.25*	−0.03	−0.06*	—			
[14] *R&D int.*	C	F	0.18	0.39	−0.07†	0.22*	0.10	−0.37*	−0.10	0.03	0.04	0.16*	−0.01	0.09*	−0.18*	0.06†	0.19*	—		
[15] ln(*Cap. int.*)	C	F	5.54	0.60	−0.17*	0.17*	0.08	0.02	−0.05	0.08*	0.06	0.12	−0.03	0.07*	−0.19*	0.04	0.09*	0.31*	—	
[16] *Tobin's Q*	C	F	2.54	1.63	0.04	0.37*	0.23*	0.04	0.10	0.07*	0.07	0.15	0.01	0.16*	0.04	0.03	0.08*	0.31*	0.26*	—
[17] ln(*#of plants*)	C	F	0.86	0.44	−0.10*	−0.05	0.09*	0.24*	0.17*	0.05*	−0.16*	−0.22*	−0.53*	−0.11*	0.12*	−0.05†	−0.18*	−0.43*	−0.13*	−0.16*

Notes. Types are as follows: dichotomous (D) and continuous (C). Levels are as follows: inspection (I), plant (P), and firm (F). Correlations are calculated at the plant level, except for correlations with inspection outcomes, which are calculated at the inspection level. All correlations are pairwise. Correlations between dichotomous measures are polychoric correlations; correlations between dichotomous and continuous measures are polyserial correlations.

$^{*}p \leq 0.01$; $^{\dagger}p \leq 0.05$.

We tracked plants over time, capturing ownership changes. As we have multiple inspections per plant over 13 years, our firm-level data would be inaccurate if we do not track these changes. The FDA provided only limited means of keeping track of ownership changes in its inspection database. Ownership changes were tracked by searching online merger, acquisition, and spinoffs by firm name in the Thomson and ORBIS databases as well as through Google searches.

Finally, we collected data on variables to be used as instrumental variables in a supplemental analysis to partially address concerns with omitted variables bias (§5). In our setting, instrumental variables should predict whether or not a plant is colocated but should otherwise be independent of all other omitted predictors of quality performance at the plant level. We use two such variables (referred to as excluded instruments). The first is the *number of plant employees*. This variable is taken from the NETS database and represents a measure of scale for the plant. Our second instrument is a measure of the available *labor pool* at the location of the plant, obtained from the National Historical Geographical Information System. Specifically, we matched plant addresses to metropolitan area codes and downloaded the number of people employed in three relevant categories in that location (computer/math, architecture/engineering, life/physical/social sciences). Since numbers across categories were highly correlated (Cronbach's alpha $= 0.85$), we used the simple average across the categories as our estimate of the size of the labor pool in the location. This metric has a moderate correlation ($r = 0.38$) with *population density*, one of our other control variables. Note that we also collected the average *wage rate* in an area from the same data source. This measure was considered as an additional instrument, but since it predicted manufacturing quality outcomes, we use it as an additional control variable instead.

Table 3 **Descriptive Analysis**

Category	% adverse	Inspections	p-value
All plants	18	8,832	
Colocated plant	16	2,959	$p \leq 0.01$
Noncolocated plant	20	5,873	
Large firm, colocated plant	12	978	$p \leq 0.01$
Large firm, noncolocated plant	20	1,008	
Small firm, colocated plant	13	580	$p \leq 0.10$
Small firm, noncolocated plant	16	1,242	
Tacit process, colocated plant	14	974	$p \leq 0.01$
Tacit process, noncolocated plant	22	1,242	
Nontacit process, colocated plant	18	1,375	$p = 0.84$
Nontacit process, noncolocated plant	18	3,429	
After year 2000, colocated plant	11	1,417	$p \leq 0.01$
After year 2000, noncolocated plant	16	2,707	
Up to year 2000, colocated plant	20	1,542	$p \leq 0.01$
Up to year 2000, noncolocated plant	23	3,166	
High bandwidth, colocated plant	13	427	$p \leq 0.01$
High bandwidth, noncolocated plant	18	679	
Low bandwidth, colocated plant	12	1,221	$p \leq 0.05$
Low bandwidth, noncolocated plant	15	1,724	

Notes. "Adverse inspections" indicates the proportion of inspections within that category leading to an official action outcome. The reported p-values are the result of a two-sample test of proportions comparing the proportion of adverse inspections for colocated plants with the related proportion in a sample of noncolocated plants in the succeeding row.

4. Analysis

4.1. Descriptive Analysis

We first report descriptive statistics by comparing the occurrence of adverse inspection outcomes in different subsamples. An overview of this analysis is given in Table 3. The proportion of adverse inspection outcomes among colocated plants (16%) is lower than the proportion of adverse inspection outcomes among noncolocated plants (20%). Furthermore, this difference becomes more pronounced for large firms, in which colocated plants show many fewer adverse inspection outcomes (12%) than noncolocated plants (20%). In smaller firms, colocated plants have only slightly fewer adverse inspection outcomes (13%) than noncolocated plants (16%). Similar to large firms, plants with tacit process knowledge have many fewer adverse outcomes when they are colocated (14%) than when they are not colocated (22%), a difference that entirely disappears for plants with low levels of tacit process knowledge (18% versus 18%). However, when we look at the samples of inspections occurring early versus late in our data set and the samples of plants with high and low Internet bandwidth, we notice that colocation matters more or less uniformly across samples. For example, among those plants with high Internet bandwidth, colocated plants have a 13% chance for an adverse inspection outcome; noncolocated plants have an 18% chance. Among plants with little Internet bandwidth, these proportions are 12% versus 15%. These descriptive statistics are consistent with H1, H3, and H4B and indicate that H2 (and H4A) may not be supported.

4.2. Main Model and Estimation

We use a probit model to explain inspection outcomes with inspection-, plant-, and firm-level variables. Our data have a multilevel structure (multiple inspections per plant, and multiple plants nested in firms), which we tried to estimate via multilevel probit models; however, since these estimations often did not converge, and since the firm level rarely explained variance beyond the plant level, we only report two-level model estimation results, with inspections nested in

Table 4 **Probit Regression on** *Inspection Outcome*

	Model 1		Model 2		Model 3		Model 4		Model 5	
	Est.	SE	Est.	SE	Est.	SE	Est.	SE	Est.	SE
Inspection level										
Year (not reported)										
Previous inspection adverse (*PIA*)	0.80^{**}	(0.28)	0.82^{**}	(0.28)	1.19^{*}	(0.61)	$1.17^{\dagger}$	(0.63)	0.82	(0.82)
ln(*Time since last inspection*)	0.12^{**}	(0.03)	0.12^{**}	(0.03)	$0.09^{\dagger}$	(0.05)	0.06	(0.05)	0.02	(0.07)
PIA × ln(*Time since last inspection*)	−0.04	(0.05)	−0.04	(0.05)	−0.14	(0.11)	−0.14	(0.12)	−0.08	(0.15)
Consumer complaint inspection	-0.66^{**}	(0.20)	-0.67^{**}	(0.20)	$-0.84^{\dagger}$	(0.49)	−0.78	(0.50)	−0.68	(0.50)
Surveillance inspection	-0.41^{**}	(0.05)	-0.41^{**}	(0.05)	-0.45^{**}	(0.09)	-0.39^{**}	(0.09)	-0.47^{**}	(0.12)
Plant level										
ln(*Inspection frequency*)	0.20^{**}	(0.05)	0.22^{**}	(0.05)	0.23^{**}	(0.09)	0.24^{**}	(0.10)	0.30^{*}	(0.13)
Cluster	−0.02	(0.06)	−0.02	(0.06)	0.16	(0.11)	0.12	(0.11)	0.05	(0.13)
Headquarter	$0.11^{\dagger}$	(0.06)	0.13^{*}	(0.07)	0.15	(0.10)	$0.17^{\dagger}$	(0.10)	0.20^{*}	(0.10)
Standalone	0.29^{**}	(0.06)	0.27^{**}	(0.06)	0.12	(0.12)	0.14	(0.10)	0.26^{*}	(0.12)
ln(*Population density*)	0.06^{**}	(0.02)	0.06^{**}	(0.02)	$0.07^{\dagger}$	(0.04)	0.09^{*}	(0.04)	0.13^{**}	(0.04)
ln(*Wage rate*)	-0.51^{**}	(0.16)	-0.47^{**}	(0.16)	-1.03^{**}	(0.27)	-1.11^{**}	(0.25)	-1.44^{**}	(0.30)
ln(*Plant age*)									$0.12^{\dagger}$	(0.07)
Credit score									$0.01^{\dagger}$	(0.01)
Colocated			-0.13^{*}	(0.06)	−0.01	(0.16)	0.13	(0.16)	0.67^{**}	(0.23)
Tacit process (*TP*)					0.28^{**}	(0.11)	0.23^{*}	(0.10)	0.41^{**}	(0.41)
Colocated × *Tacit process*					-0.40^{*}	(0.17)	$-0.32^{\dagger}$	(0.17)	-0.83^{**}	(0.22)
Firm level										
R&D intensity							$-0.95^{\dagger}$	(0.59)	-2.42^{**}	(0.79)
ln(*Capital intensity*)							-0.21^{**}	(0.08)	-0.18^{*}	(0.10)
Tobin's Q							−0.02	(0.03)	$-0.07^{\dagger}$	(0.04)
ln(*Number of plants*)							0.05	(0.06)	0.08	(0.08)
Large firm (*LF*)					0.14	(0.11)	0.01	(0.11)	0.13	(0.14)
Colocated × *Large firm*					$-0.34^{\dagger}$	(0.18)	-0.42^{**}	(0.17)	-0.66^{**}	(0.24)
High bandwidth					-0.35^{**}	(0.13)	$-0.21^{\dagger}$	(0.13)	-0.25^{*}	(0.12)
Colocated × *High bandwidth*					0.24	(0.24)	0.10	(0.23)	−0.11	(0.25)
Constant	3.69^{*}	(1.71)	$3.26^{\dagger}$	(1.73)	9.19^{**}	(2.92)	11.16^{**}	(2.70)	13.25^{**}	(2.80)
Marginal effect of colocation			-0.03^{*}	(0.01)	-0.08^{**}	(0.02)	-0.07^{**}	(0.02)	-0.06^{*}	(0.03)
(*conditional on TP, LF*)					-0.17^{**}	(0.04)	-0.14^{**}	(0.04)	-0.19^{**}	(0.05)
(*conditional on TP, non-LF*)					-0.09^{*}	(0.04)	−0.04	(0.04)	−0.04	(0.05)
(*conditional on non-TP, LF*)					-0.07^{*}	(0.03)	$-0.06^{\dagger}$	(0.03)	0.00	(0.05)
(*conditional on non-TP, non-LF*)					0.00	(0.03)	0.03	(0.04)	0.15^{**}	(0.06)
χ^2	456.43		460.41		324,44		338.20		555.64	
Pseudo R^2	0.10		0.10		0.16		0.17		0.23	
N (inspections/plants/firms)	5,753/911/672		5,753/911/672		1,711/230/78		1,562/201/76		1,033/140/69	

Notes. The conditional marginal effects in Models 3–5 are estimated in mutually exclusive groups, despite the models not allowing the effect of colocation to change freely across all of these groups. However, adding the necessary interactions $TP \times LF$ and $TP \times LF \times Colocated$ to the models does not change the reported estimates fundamentally.

$^{*}p < 0.05$; $^{**}p \leq 0.01$; $^{\dagger}p \leq 0.10$.

plants.[6] We model this two-level structure by estimating clustered standard errors at the plant level. This approach is generally quite robust to misspecifications, particularly compared to random effects models (Angeles et al. 2005). We explore random and fixed effects models as robustness tests later.

A key trade-off in our model is that adding control variables into the analysis reduces the set of complete observations. We therefore estimate different models that successively add more variables to analyze our data. Results from our estimation are summarized in Table 4. Models 1 and 2 are estimated on a broad data set but only include basic plant- and inspection-level control variables (Model 1) and our main independent variable, *colocated* (Model 2). Models 3, 4, and 5 are estimated on reduced data sets but contain our key moderators (Model 3), firm-level variables (Model 4), and additional control variables at the plant level (Model 5). All of these models were estimated using the probit procedure in Stata 13.1 with clustered standard errors. We consider Model 3 our main model for interpretation; Models 4 and 5 are mostly included to provide evidence for robustness of our results in different subsamples including added control variables.

[6] Several factors contribute to the difficulties of estimating three-level models in our context. First, most firms have only one or two plants in our data set. Second, plants are not necessarily nested within one firm but can change firms through our study period through mergers and acquisitions.

The estimates from Model 2 provide support for H1. Colocated plants have a significantly lower risk of receiving an adverse inspection outcome. Our estimated average marginal effects (with continuous covariates fixed at their averages, and categorical covariates fixed at their most frequent category) of *colocated* indicate that the reduction in risk for colocated plants is approximately 3 percentage points—an effect similar to the simple comparison in Table 3 (i.e., 4 percentage points). Our analyses in Models 3–5 support H3 and H4B. In particular, the interaction effects between *colocated* and *tacit process*, as well as the interaction effect between *colocated* and *large firm*, are negative and significant

Models 3–5 do not provide support for H2. There is no significant interaction effect between *colocated* and *high bandwidth*. Although *high bandwidth* has a direct effect on quality risk (such that high-bandwidth firms have about a 5 percentage point lower risk of an adverse inspection outcome than low-bandwidth firms), the effect of colocation is unaffected by the bandwidth available. An alternative measure of ICT penetration is to rely on the natural temporal diffusion of ICTs and split our sample into early (i.e., before 2000) and late (i.e., during and after 2000) inspections. We re-estimated Model 3 with this alternative measure of ICT penetration (*Early*) and again found no significant interaction effect between this variable and colocation ($b = 0.09$, $p = 0.62$).

Our analysis in Model 5 also points to several interesting control variables. *Population density* appears as a fairly strong predictor of inspection outcomes ($b = 0.13$, $p \leq 0.01$), indicating that urban plants tend to operate with lower conformance quality than more rural plants. Rural plants tend to have a more stable workforce, which corresponds to both more job-specific experience and lower turnover. This lower turnover may be related to higher conformance quality (Ton and Huckman 2008). All practitioners we interviewed as part of our research explained that this result matched their experience, noting that "rural kids" are more likely to be "used to fixing things." Jeff Owens, head of a contract skilled worker firm that fills manufacturing roles, noted, "If they grew up on a farm… that has been very good for us" (Hagerty 2014). Furthermore, we note that *wage rate* at the area where the plant is located also impacts *inspection outcomes*, such that plants in regions with higher wages also had a lower likelihood of adverse inspection outcomes ($b = -1.44$, $p \leq 0.01$). One explanation is that higher wages probably relate to higher productivity and/or education levels among the workforce. Among the firm-level variables, *R&D intensity* relates to better quality performance ($b = -2.42$, $p \leq 0.01$, Model 4). This finding is supportive of the overall idea of complementarities between manufacturing and R&D and could indicate that higher R&D expenses lead to a generally higher ability of firms to solve manufacturing problems as well. *Capital intensity* also has a strong beneficiary effect on quality performance ($b = -0.18$, $p \leq 0.01$, Model 4), indicating that firms that use more automated processes have overall better quality performance. This is consistent with previous research, which has shown that implementing quality management practices is less important in firms with high capital intensity (Hendricks and Singhal 2001).

A closer look at the conditional marginal effects of *colocated* based on an analysis of different subsamples representing different combinations of *plant size* and *tacit process* reveals that colocation matters most in plants that belong to both large firms and plants with processes requiring high levels of tacit knowledge. For such firms, effect sizes here indicate that the likelihood of adverse inspection outcomes for colocated plants drops by more than 14 percentage points relative to noncolocated plants. The marginal effect for plants that have either a tacit knowledge process or that belong to a large firm is much smaller (4–8 percentage points) and is not significant in some models (particularly Model 5). Note that Model 5 also shows that, for plants that both use nontacit knowledge and belong to small firms, *colocated* relates to an increased propensity to obtain an adverse inspection outcome ($b = 0.67$, $p \leq 0.01$). However, this effect is dependent on the sample/method used for analysis and is not robust (e.g., it is not present in Models 3 or 4); it should therefore be interpreted with care.[7]

4.3. Model Robustness

As a first robustness test, we estimated all models as (1) a random effects probit model, with inspections nested in plants, and (2) a multilevel mixed effects logit model, with inspections nested in plants nested in companies. Our main analysis used a simple probit model with clustered standard errors. The results from these additional estimations were comparable to the estimates reported in Table 4. As a second robustness test, we used multiple imputation methods to estimate the missing values for *tacit process*, *large firm*, and *high bandwidth* to measure Internet connectivity. More precisely, in a chained estimation

[7] We note that it is the inclusion of interaction terms, *not* the change in sample from model to model, that results in *colocated*'s first-order effect changing from negative and significant in Model 2, to nonsignificant in Models 3–4, to positive and significant in Model 5. If Model 2 is run for the samples used in Models 3–5, *colocated* remains negative and significant. Relatedly, the coefficients of *colocated* in Models 3–5 should not be construed as lack of support for H1. Rather, they are evidence of the contingent nature of the observed first-order relationship. Indeed, if all moderating variables were reverse coded, the coefficient of *colocated* would be negative and significant for each of Models 3–5.

approach, we predicted missing values in 50 imputed data sets for these three moderators, using ln(*audit frequency*), *plant type*, ln(*population density*), ln(*wage rate*), and ln(*number of plants*) as universally available predictors. Having made these imputations, we then reestimated Model 3 using a simple probit model with clustered standard errors. The results from this analysis were mostly consistent with Table 4, with the exception that the interaction effect between *colocated* and *large firm* becomes insignificant ($p = 0.20$). A possible explanation may be that the added sample of imputed plants in this analysis mostly consists of small, private company plants which add little information (but, through the imputation procedure, a lot of noise) to the estimation of this interaction effect.

To further test whether the effect of colocation depends on the nature of R&D activities occurring at the plant and the firm, we collected three more patent-related measures at the plant level from the Thomson Innovation database: the total patent count at the plant in the last five years, the percentage of total patents that were process patents (as opposed to product patents) at the plant each year, and the count of patent classes represented among these patents. We created the natural logs of these variables (+1), such that noncolocated plants naturally score a zero value on these variables, and then added all of these variables to Model 2. This allows us to test whether R&D activities that are larger in scale and more product oriented and focused create more or less benefit of colocation. None of these variables were significant in the analysis, indicating that the benefits of colocation are relatively universal across these different types of plant and firm R&D activities.

Our dependent variable currently measures a relatively rare event—an official action outcome is indicated in only 18% of inspections. More often, the FDA issues a voluntary action outcome (40% of inspections). Similarly, inspectors have the power to issue a Form 483 to the plant if they have observed quality issues at the plant. This happens fairly frequently (55% of inspections), but in more than 90% of cases, this coincides with either an official (30%) or voluntary (64%) action district decision. We could, therefore, change our dependent variable to indicate (i) whether a voluntary or official action outcome is issued by the district, or (ii) whether a Form 483 is issued by the inspector. We re-estimated Models 2 and 3 with these two alternative dependent variables. Both estimations from Model 2 show a smaller effect of colocation that is only weakly significant ($p \leq 0.10$). Estimates from Model 3 for both dependent variables support an interaction effect between *colocated* and *large firm*, consistent with H4B ($p \leq 0.05$), but the interaction effect between *colocated* and *tacit process* becomes nonsignificant in both models ($p = 0.23$ and $p = 0.39$). This could indicate that the improvements in conformance quality through colocation in tacit process knowledge plants are limited to a reduction in major instances of noncompliance (which call for official action from the FDA) and do not extend to more minor deviations. In our assessment, this nonresult is likely driven by the fact that, per a panel of experts employed for other research using FDA data (Gray et al. 2011, Appendix A), official action outcomes signal a much higher level of noncompliance than voluntary action outcomes do. Specifically, the experts coded the difference between official action and voluntary action as six times greater than the difference between voluntary action and no action. Interestingly, though, the same analysis also reveals that the interaction effect between *colocated* and *high bandwidth*, which was previously not significant, now becomes positively significant ($p \leq 0.10$). A closer look at the conditional marginal effect shows that *colocated* has no significant effect on the likelihood of observing a 483 form for an inspection across small and large bandwidth plants ($b = -0.02$, $p = 0.55$ and $b = 0.06$, $p = 0.27$), but that bandwidth matters much more if plants are not colocated. Our analysis particularly shows that *high bandwidth* in noncolocated plants relates to a 13 percentage point reduction in the risk of being issued a Form 483 ($p \leq 0.01$), whereas firm bandwidth makes no difference on this risk in colocated plants ($p = 0.86$). This observation indicates that ICTs may help noncolocated plants prevent minor quality issues but have little effect in avoiding larger levels of noncompliance.

As discussed in §3, plants were classified as colocated if they met any of three criteria: (1) a patent generated by the firm in the same city as the plant, (2) a secondary or tertiary SIC code from the NETS database indicating R&D activity, or (3) the presence of patent-generating activity by the plant's firm occurring within 50 miles of the plant. We examined whether the effect of colocation holds for each of these criteria individually. To do so, we re-estimate Model 2 for a sample of plants that either have tacit process knowledge or that belong to large firms (2,479 audits in 279 plants). The results show that *colocated*, as expected, has a significant effect in this sample. We then allow this effect to vary, depending on the category according to which the plant was classified as *colocated*, and perform a likelihood ratio test between these two models (i.e., one model with constrained parameters across the three samples and one with unconstrained parameters). The results show that the model with free parameters depending on category does not fit the data significantly better than the constrained model ($\chi^2 = 0.31, p = 0.86$), indicating that the effect of colocation is approximately similar across these three categories.

We currently categorized all plants that are less than 50 miles away from a plant with patents as colocated and all other plants as noncolocated. Here, we do not classify such plants as colocated, and instead estimate an effect of the (natural log) of the linear distance between a (noncolocated) plant and a location with patents. To complete this analysis, we need to add an additional variable into the equation, which measures the (natural log of) the number of parent firm patents during the preceding five years. This naturally differentiates plants that belong to firms that have no patent activity at all. We can then code the distance to R&D as 0 for all colocated plants as well as for all plants that have no firm patents. For all remaining plants, we record the natural log of the distance in miles. The results from our estimation show a positive and significant effect of distance ($b = 0.03$, $p \leq 0.05$), indicating that the farther away a plant is from R&D activity, the higher the likelihood of that plant getting an adverse inspection outcome.

The next set of robustness tests relate to H2 concerning ICT penetration. Our measure of ICT penetration (*high bandwidth*) originates from firm-level data from the year 2008, but we also have more detailed (and longitudinal, 2001–2007) site-level data available from Harte-Hanks. These detailed data are available for only about 110 plants in our data set, but we can use it as an additional robustness test on H2. We estimated Model 2 with an additional interaction effect between colocation and site-level bandwidth—either in continuous form or dichotomized for the highest quartile. In neither case was the interaction effect statistically significant (colocation remained significant). Furthermore, instead of using our existing measure of firm bandwidth to examine two different groups (high bandwidth as the highest quartile versus the rest) we split the sample into four equal-sized groups along quartiles to measure whether colocation has an effect in any quartile. To do so, we estimated Model 2, with only the added interaction effect of this measure and colocation. The results show a significant interaction effect of the highest quartile of bandwidth (compared to the lowest quartile of bandwidth), such that the difference in the likelihood of an adverse inspection outcome going from very low to very high bandwidth for colocated plants is 8 percentage points greater than the same difference for noncolocated plants. This result is in the opposite direction of that proposed in H2; we expected that colocation would matter less, and not more for plants with greater access to ICTs. A similar analysis with a continuous measure for Internet penetration reveals no significant interaction effect ($b = -0.05$, $p = 0.31$).

For H3, all plants in the main analysis whose level of tacit production knowledge score exceeded 5 were coded as having tacit process knowledge. This included various classifications of products such as biological products, vaccines, parenterals and aerosols. This was, however, a fairly exclusive specification, since only about 20% of our plants fell into this category. To more broadly examine the robustness of our test of H3, we reestimated Model 2, adding an interaction effect between our continuous measure of tacit process knowledge and colocation. The resulting estimation shows a significant interaction effect ($b = -0.11$, $p \leq 0.05$). Furthermore, we approximately coded our sample into quartiles along the level of tacit process knowledge score, with the lowest quartile containing categories such as medical gas and nonsterile liquids, the second lowest containing ointments and prompt release tablets, the third lowest containing gelatin capsules, delayed/extended release tables and the highest quartile being equivalent to our original group. We reestimated Model 2 with this added interaction effect. The results show that colocation has a significant marginal effect in the group with the highest level of tacit process knowledge ($b = -0.05$, $p \leq 0.05$) and no marginal effect in the other groups ($= 0.03$, $p = 0.30$, in the lowest group, $= -0.02$, $p = 0.55$ and $= -0.02$, $p = 0.36$ in the second and third lowest groups).

Our previous scoring of the level of tacit production knowledge was based mostly on the product categories provided by the FDA, but on a few occasions when product categories were unavailable, we supplemented those data using industry classifications by the FDA. To test whether this decision influenced our results, we categorized plants as having tacit process knowledge only if we had evidence from FDA product categorizations, and we reran a simple probit model with clustered standard errors (as in the previous paragraph) to estimate the effect of colocation in these different categories (3,705 inspections in 464 plants). Again, our analysis remains robust, since the plants with tacit processes show a significant marginal effect ($b = -0.05$, $p \leq 0.05$), and the other plants do not show this effect ($b = 0.01$, $p = 0.07$).

To examine the robustness of our test of H4B, we used alternative measures of firm size. In particular, we recorded firm-level revenues in the year 2010, as recorded in either the COMPUSTAT, Dun and Bradstreet, or ORBIS databases. This measure was almost universally available. We reestimated Model 2 with additional interaction effects between (the natural log of) this variable and colocation; the results from this estimation show little support for an interaction effect ($b = 0.01$, $p = 0.57$). We repeated this analysis by categorizing firms into quartiles using this variable. The effect of colocation was only weakly significant in the highest quartile of firm sales, with a marginal effect of a 4 percentage point reduction in the risk of adverse inspection outcomes ($p \leq 0.10$). It thus seems that the effects of colocation are really only present for the largest firms; even medium-sized firms do not gain the benefits of colocation. Note that firm size and tacit process knowledge do not necessarily go hand in hand; only 32% of our tacit process knowledge plants belong to firms in the highest quartile of revenues.

In summary, we have found evidence that our main hypotheses are reasonably robust. Colocation maintains an effect throughout most models. Furthermore, there is scant evidence that alternative measures for ICTs change the empirical finding that ICTs have little or no influence on the effectiveness of colocation. The moderation effects of firm size and tacit process knowledge are mostly present in all of our robustness tests. The hypothesized effects of colocation are strongest among plants that belong to large firms and that require tacit process knowledge.

4.4. Endogeneity

Colocating a plant is an organizational decision, and as such, it is not exogenous to our model. This creates the potential for omitted variables bias in our estimates. Our study is correlational in nature and does not represent a natural experiment. This limits our ability to ultimately draw causal inference from our study. However, we employ several robustness tests in this section that strengthen our confidence that the relationship between colocation and quality performance is not spurious. None of these analyses changes the correlational nature of our study, but they add confidence in the robustness of our results.

Our first robustness test in these regards is an instrumental variables approach to predict colocation in addition to inspection outcomes. Our objective here is to test whether Model 2 and the support for H1 change once we control for unobserved heterogeneity. Since the methods we need for that purpose are large sample methods, we want to use a broad sample for these tests, but we also add additional control variables at the firm level to reduce omitted variable bias in the estimation. Toward that goal, we modify Model 2 by adding three firm-level control variables—the total patent volume of the firm in the preceding five years, the number of plants of the firm recorded in the FDA data set, and the revenue of the firm recorded in the ORBIS database as of 2010, the year we accessed this data. These three control variables were readily available throughout the sample and increase our confidence that our excluded instruments do not correlate with unobserved effects on inspection outcomes.

The two excluded instrumental variables we use for identification were introduced in §3. The first instrument is the (natural log of) the *number of plant employees* at the plant. An executive who commented on an earlier draft of our paper stated that "given the fixed infrastructure costs for large-scale manufacturing facilities ... the addition of R&D staff can come at a small marginal cost, where those same engineers in a dedicated [noncolocated] facility would incur much more overhead for the same work." This variable correlates well with *colocated* (polyserial $r = 0.38$, $p \leq 0.01$), and adding this variable to our model indicates that it has no significant effect on quality performance ($b = -0.02$, $p = 0.30$). This observation is consistent with some prior research (Gray et al. 2011, Squire et al. 2006). Studies have found plant size to have a positive relationship with quality-related measures (Ball et al. 2015, Gray et al. 2015), but these papers do not have firm-size controls and therefore are likely capturing effects related to the resources that large firms provide. This is a key reason we added additional firm-level variables to Model 2 for this analysis. Taken together, conceptually and empirically, plant size meets the criteria for a valid instrument, given our control variables.

The second instrument we use relates to the relevant *labor pool* in the metropolitan area associated with the plant's zip code. Specifically, the natural log of this measure correlates with colocation (polyserial $r = 0.16$, $p \leq 0.01$) but has little effect on *inspection outcomes* when added to our base model ($b = -0.01$, $p = 0.78$). In general, R&D activities are probably more likely to be located where a larger labor pool for R&D work exists; plants that are located in an area with such a labor pool are therefore more likely to be designed as (or turned into) colocated plants. Note that *labor pool* correlates with *wage rate* ($r = 0.72$, $p \leq 0.01$), which in turn correlates with *inspection outcomes*, and we thus control for wage rates in our analysis as well.

We first estimate a two-stage model in which *colocated* is estimated in the first stage at the plant level, and predicted probabilities for *colocated* are then used in the second stage to predict inspection outcomes at the inspection level. This model allows us to naturally reflect the hierarchical nature of our data and also enables us to further test our instruments for identification. Results are reported in Table 5.

The first-stage model shows that both excluded instruments significantly relate to *colocated*; a joint test for both instruments having no relationship with colocation rejects the null hypothesis ($\chi^2 = 31.78$, $p \leq 0.01$). Other included instruments show effects in the expected direction; for example, *firm headquarters* are more likely to be colocated plants, and plants in firms that have a more plants in their network are less likely to be colocated. Note that we did not include *wage rate* in this first-stage equation, since *wage rate* is highly correlated with *labor pool*. We then proceeded to record predicted probabilities of colocation for each plant and use these predicted probabilities in

Table 5 Two-Stage Probit and Bivariate Probit Regression on *Inspection Outcome*

Estimation procedure:	Probit		Two-stage probit				Bivariate probit				Fixed effects logit	
Dependent variable:	*Inspection outcome*		*Colocation*		*Inspection outcome*		*Colocation*		*Inspection outcome*		*Inspection outcome*	
	Est.	SE	Est.	SE	Est.	SE	Est.	SE	Est.	SE	Est.	SE
Inspection level												
Year (not reported)												
Previous inspection adverse (*PIA*)	0.81**	(0.28)			0.79**	(0.28)			0.80**	(0.28)	2.34**	(0.41)
ln(*Time since last inspection*)	0.11**	(0.03)			0.11**	(0.03)			0.10**	(0.02)	0.25**	(0.05)
PIA × ln(*Time since last inspection*)	−0.05	(0.05)			−0.04	(0.05)			−0.05	(0.05)	−0.48**	(0.07)
Consumer complaint inspection	−0.63**	(0.20)			−0.62**	(0.20)			−0.62**	(0.19)	−1.12**	(0.37)
Surveillance inspection	−0.40**	(0.05)			−0.40**	(0.05)			−0.40**	(0.05)	−0.50**	(0.08)
Plant level												
ln(*Inspection frequency*)	0.50**	(0.11)	0.81**	(0.18)	0.61**	(0.14)	0.33	(0.27)	0.55**	(0.13)		
Cluster	−0.01	(0.07)	−0.08	(0.12)	0.00	(0.07)	−0.16	(0.16)	−0.01	(0.07)		
Headquarters	0.02	(0.07)	0.44**	(0.13)	0.07	(0.08)	0.30†	(0.18)	0.06	(0.08)		
Standalone	0.07	(0.07)	−0.26†	(0.14)	0.06	(0.07)	−0.35*	(0.17)	0.04	(0.07)		
ln(*Population density*)	0.05*	(0.02)	−0.06	(0.04)	0.05**	(0.02)	−0.04	(0.05)	0.05**	(0.02)		
ln(*wage rate*)	−0.75**	(0.17)			−0.71**	(0.18)			−0.64**	(0.19)		
ln(*Labor pool*)			0.13**	(0.03)			0.19**	(0.05)				
ln(*Num. of plant employees*)			0.16**	(0.03)			0.20**	(0.05)				
Colocated	−0.13*	(0.06)			−0.40†	(0.23)			−0.40*	(0.21)	−2.03*	(0.06)
Firm level												
ln(*Firm patents*)	0.03**	(0.01)	0.14**	(0.02)	0.04**	(0.01)	0.13**	(0.03)	0.04**	(0.01)	0.00	(0.04)
ln(*Plants in firm*)	−0.03	(0.03)	−0.26**	(0.07)	−0.05	(0.04)	−0.11	(0.08)	−0.04	(0.04)	0.04	(0.19)
ln(*Firm sales*)	−0.06**	(0.01)	0.00	(0.02)	−0.05**	(0.01)	−0.04	(0.03)	−0.05**	(0.01)	0.03	(0.06)
Constant	7.28**	(1.88)	−2.49**	(0.40)	6.74**	(2.00)	−2.99**	(0.56)	6.16**	(2.05)	—	—
Marginal effect of colocation	−0.03*	(0.01)			−0.09**	(0.06)			−0.09*	(0.05)		
χ^2	496.88		193.58		503.58		636.21				174.16	
Pseudo R^2	0.11		0.18		0.11		—				—	
N (inspections/plants/firms)	5,630/895/615		–/895/615		5,630/895/615		5,630/895/615				4,673/502/449	

$^{*}p < 0.05$; $^{**}p \leq 0.01$; $^{\dagger}p \leq 0.10$.

the second-stage equation (in lieu of actual values for colocation) to predict adverse inspection outcomes. Results show that *colocated* retains weak significance in the second-stage equation. The effect size of *colocated* roughly triples (compared to the simple probit model), but the standard error of colocation quadruples (due to the two-stage estimation procedure).

We estimate deviance residuals from the second-stage estimation and regress these residuals on our excluded instruments. The resulting R^2 is very low (0.0002). We calculated the Sargan test statistic (1.12), which is not statistically significant ($p = 0.29$), indicating that the error term of the second stage is indeed uncorrelated with the excluded instruments, supporting their validity. To address concerns that our two-stage estimation may constitute a "forbidden regression" due to the nonlinear nature of the underlying probit models, we also estimated a bivariate probit model in which both equations were estimated simultaneously via maximum likelihood. The method we used for that purpose is the "biprobit" routine in Stata, with standard errors clustered by plants. Results from this estimation reported in Table 5 show that *colocated* has a significant impact on *inspection outcomes* ($p \leq 0.05$). The correlation of regression error terms between equations is not significant ($\rho = 0.17$, $p = 0.17$), indicating that there was little endogeneity in our analysis. We can see from a comparison of marginal effects that the marginal effect of *colocated* in both the two-stage estimation and the simultaneous estimation is stronger (9 percentage points) than in the simple probit estimation (3 percentage points), indicating that, if unobserved heterogeneity biased our main results, it is more likely to have suppressed these effects rather than increased them.

Beyond these instrumental variables approaches, we also estimated a fixed effects model to control for unobserved plant-level effects. Note that, as detailed earlier, the within-plant variation of *colocated* is very limited and, therefore, the fixed effects model should be interpreted with extreme caution. We need to estimate a logit model instead of a probit model, since probit fixed-effect estimators are notoriously challenging, particularly with only a small number of observations per plant (Heckman 1981). We employ the "xtlogit" procedure with the fixed effects option in Stata. Note that (i) we removed all plant-level control variables from this analysis and that (ii) the procedure drops all plants from the analysis that have either all or no adverse inspection outcomes in our record history. The estimation results are summarized in Table 5; they again show a significant effect of *colocated* in the predicted direction. We note again that only nine plants had within-plant variation in *colocated*, making it difficult to interpret the actual effect size.

Finally, we present a set of matching analyses, particularly nearest neighbor matching, propensity score matching (e.g., Gopal et al. 2013), and coarsened exact matching (King et al. 2011). In these analyses, colocated plants are matched according to some observable criteria to noncolocated plants, facilitating a fair comparison of colocation effects (Abadie and Imbens 2012). Since these analyses need to take place at the plant level, we calculate the percentage of adverse inspections at the plant level as a measure of plant-level quality performance. We use *inspection frequency*, *population density*, and *number of employees* at the plant as matching variables in all analyses. These variables were both broadly available throughout our data set and significantly related to *colocated*. Nearest neighbor matching and propensity score matching were completed using the "teffects" procedure in Stata; coarsened exact matching was accomplished by using the user-generated Stata procedure "cem." To extend our analysis beyond H1, we also conduct these matching analyses in subsamples of our data to further examine H2 and H3. For example, to retest H2, we repeat all matching analyses among plants with high company bandwidth as well as in plants with low company bandwidth. The results from all analyses are summarized in Table 6. Across all matching methods, *colocated* retains an effect, further supporting H1. The treatment effects estimated here tend to be higher than the treatment effects estimated in Model 2 in Table 4. We note that treatment effects tend to be stronger for plants from high bandwidth firms than those from low bandwidth firms, which is counter to H2. Treatment effects are also visible in large firm plants and nonexistent for small firm plants, further supporting H4B. Similarly, the treatment effects of colocation appear clearly among tacit knowledge plants and are mostly absent in nontacit knowledge plants, consistent with H3. Overall, these observations are consistent with our earlier analyses. Note that we also estimated treatment effects of *colocated* in the subsample of nontacit small firm plants. While these treatment effects are positive, as in Model 5 in Table 4, they are not statistically significant here.

Table 6 Matching Analysis

	ATE	SE	Plants
Sample: All plants (H1)			
Nearest neighbor	−0.05*	(0.02)	1,119
Propensity score	−0.04**	(0.02)	1,119
Coarsened exact	−0.06**	(0.02)	752
Sample: High bandwidth (H2)			
Nearest neighbor	−0.12**	(0.03)	91
Propensity score	−0.05†	(0.03)	91
Coarsened exact	−0.18**	(0.05)	64
Sample: Low bandwidth (H2)			
Nearest neighbor	−0.05**	(0.02)	374
Propensity score	−0.03†	(0.02)	374
Coarsened exact	−0.03†	(0.02)	362
Sample: Tacit knowledge (H3)			
Nearest neighbor	−0.06*	(0.03)	174
Propensity score	−0.07*	(0.03)	174
Coarsened exact	−0.09**	(0.03)	143
Sample: Nontacit knowledge (H3)			
Nearest neighbor	−0.01	(0.02)	638
Propensity score	−0.02	(0.02)	638
Coarsened exact	−0.04	(0.02)	407
Sample: Large firms (H4A and H4B)			
Nearest neighbor	−0.11**	(0.02)	196
Propensity score	−0.11**	(0.02)	196
Coarsened exact	−0.11**	(0.03)	164
Sample: Small firms (H4A and H4B)			
Nearest neighbor	0.00	(0.03)	288
Propensity score	−0.01	(0.03)	288
Coarsened exact	−0.01	(0.03)	189
Sample: Small firms and nontacit			
Nearest neighbor	0.01	(0.04)	143
Propensity score	0.05	(0.04)	143
Coarsened exact	0.04	(0.04)	82

Note. ATE, average treatment effect.
$^*p < 0.05$; $^{**}p \leq 0.01$; $^{\dagger}p \leq 0.10$.

5. Discussion and Conclusion

Our study examines the effect of colocating manufacturing and R&D activities on manufacturing conformance quality performance. We examine the pharmaceutical industry, where manufacturing conformance quality is critical because failure to meet quality standards can have significant public health implications and create high economic costs. The most often-discussed benefits of R&D–manufacturing colocation relate to innovation-related performance dimensions, but our study shows that such benefits extend to manufacturing conformance quality performance as well. This finding is consistent with our hypothesis but runs counter to recommendations to separate the R&D and manufacturing organizational units at the operational level (Chandrasekaran et al. 2012). Surprisingly, the benefits from colocating R&D activities with manufacturing plants remain stable across time and the level of access to ICTs, indicating that these technologies did not substantially reduce the importance of face-to-face interaction between R&D and manufacturing during the timeframe we studied. Furthermore, we find that colocation benefits plants with high levels of tacit process knowledge and those belonging to large firms the most. Although it is not consistent across models, the analysis revealed evidence of possible detrimental effects of colocation in plants belonging to smaller firms and having low levels of tacit process knowledge. If we assume that products later in their life cycle have more codified production processes through deliberate efforts and learning (as described in, e.g., Terwiesch and Bohn 2001), then this finding supports the view that the interdependence of R&D and manufacturing is perhaps less relevant for more mature or established products (Antràs 2005, Fuchs and Kirchain 2010). Such an interpretation would be consistent with Vernon's (1966) product cycle model.

Our findings raise questions about the efficacy of collaboration and knowledge coordination across geographical distance and in the context of institutional changes. Organizational design choices—namely, noncolocated plants—that seem consistent with the institutional changes precipitated by the ICT revolution perform poorly compared to colocated plants that subscribe to the old model of face-to-face interactions. It is plausible that, despite the speed of technology-induced institutional changes, organizational processes relevant to joint problem solving across physical distance may not have evolved at the same rate. As Van de Ven et al. (2013) observe, the speed and variety of tools and software developed by ICT developers such as Apple, Microsoft, and Google are placing new demands for innovation in organizational design by the users. Relatedly, the productivity benefits of ICTs may not be easily achieved, often requiring complementary investments (Tambe et al. 2012).

The significant contingent effects—specifically with regard to firm size and the level of tacit process knowledge—demarcate the boundaries of the effects of colocation. The firm-size contingent effect implies that the coordination and joint problem-solving benefits we propose outweigh the difficulties of managing colocated sites to a greater extent in larger firms that have the experience and access to resources to manage colocated plants. The tacit process knowledge contingent effect validates the intuition that close coordination is only required when process knowledge cannot be easily codified. As our industry context is generally characterized by processes involving at least some level of tacit knowledge, it may follow that, in industries with more codified processes, manufacturing and R&D can be separated without equivalent impacts on conformance quality. Note that our analysis shows that although some benefits of colocation exist if plants either belong to large firms or have tacit process knowledge, these effects are most pronounced if both of these conditions are met.

Our research has several limitations. First, most variables are imperfect measures of the underlying constructs of interest. The inspection data we use as a dependent variable are only a coarse representation of the manufacturing conformance quality performance of the plant. Although a key goal of the inspections is to ensure conformance quality, FDA inspections are neither a direct nor precise measure of this outcome. Our measure of colocation is really a measure of geographic proximity and not a direct measure of organizational proximity. While undoubtedly correlated, it is possible that manufacturing and R&D activities that are close geographically are organizationally separated. Furthermore, some variables, including the level of tacit process knowledge inherent in the plant's products, are measured at a single point in time.

Second, the large-scale secondary data approach employed in our study does not offer a detailed look at the underlying mechanisms driving the observed effects. For instance, unobserved institutional and organizational factors could facilitate knowledge flows across interdependent activities and thereby influence productivity outcomes (e.g., Henderson and Cockburn 1996, Reynolds 2010). The anecdotes obtained from our interviews, provided throughout the paper, partially address this limitation. Regarding ICT, the time period of the data used in this research ends in 2007. Although the experts generally felt that ICTs were an inadequate substitute for face-to-face communication in interviews that took place from 2012 to 2014, ICTs have improved since 2007 and will continue to improve, possibly reaching the point at which they could act as more of a substitute for face-to-face interaction, thus significantly reducing the benefits of colocation. As such, the end date of our study may be considered a limitation to tracing the most recent developments in ICTs.

Our study explains the manufacturing quality outcomes of colocating R&D and manufacturing in the U.S. pharmaceutical industry. At a broad level, our findings illuminate whether and under what conditions physical proximity through geographical colocation of seemingly disparate but interdependent organizational units improves performance outcomes. Insights from our study hold important implications for the internationalization of R&D and manufacturing (Ketokivi and Ali-Yrkkö 2009). In particular, recent anecdotes of "reshoring" manufacturing activities may indicate a realization of the advantages of colocating R&D and manufacturing units. At the same time, it is worth continuing research that examines the negative aspects of colocating R&D within manufacturing plants, particularly in terms of the effects of decentralizing R&D, which could hinder the generation of more broadly applicable technological know-how (Argyres and Silverman 2004). To conclude, by providing a nuanced understanding of the benefits of colocation versus separation, our study offers guidance on critical operational issues and informs questions pertinent to organizational design and the ongoing internationalization of R&D and manufacturing activities.

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