

Data Directory

* *GxP: guideline for ‘Good working Practice’ pertaining to various branches of the pharmaceutical industry.*

**CSQA: Computerised System Quality Assurance*

Field Name	Data Type	Description
Vendor	CHAR (10)	Vendor number ID
Audit Status	CHAR (15)	Closed/Not in Scope/In Process/ Pending/Completed
In USA or OUS	CHAR (3)	Activity take place in United State or outside of United State
Location	CHAR(20)	In U.S: City, State Outside U.S: City, Country
Vendor Primary Contact	VARCHAR	Vendor Primary Contact Information
Vendor Secondary Contact	VARCHAR	Vendor Secondary Contact Information
VRTX Business Sponsor	CHAR	Vertex Business Sponsor initial
Service Audited	CHAR	Vertex Service
GxP Area	CHAR (3)	GCP: Good Clinical Practice audits. GLP: Good Laboratory Practice audit. GMP: Good Manufacturing Practice, audits of manufacturing sites. GDP: Good Distribution Practice, audits of distribution and logistic partners. GVP: Good Vigilance Practice, Audits of pharmacovigilance service providers

Audit Type	VARCHAR (40)	Qualification/Requalification/Requalification with Questionnaire/Questionnaire
Audit Method	VARCHAR (30)	None/On-site/Questionnaire in 2016/Questionnaire/Remote/None/TBD, on-site * CSQA did not participate
Proposed Quarter	CHAR(6)	Quarter 1/Quarter 2/Quarter 3/Quarter 4/Quarter 3 and 4
VRTX QA coordinator	CHAR(3)	QA coordinator initial
GxP Auditor	CHAR(5)	GxP auditor initial
CSQA Auditor	CHAR (5)	CSQA auditor initial
TrackWise (TW) Report Number	NUMBER (5)	TrackWise system generated reports number
Date of Intake	Date	
Date Questionnaire sent	Date	Questionnaire sent date
Date Questionnaire received	Date	Questionnaire received date
Date on Site Scheduled	Date	On-site audit date
Audit Start Date	Date	Audit process start date
Audit End Date	Date	Audit process complete date
Date Final Report Due	Date	Audit final report due date
Date of Completion	Date	Audit final report actual complete date

Date Observations sent to Vendor	Date	Observations form sent to vendor to review
Observation Responses Due	Date	Require observation response due date
Date Observation Responses Received from Vendor	Date	Actual date observation responses received from vendor
Observations	CHAR (10)	Major/Minor
Observations in TW	VARCHAR(30)	Observations outcome in TrackWise
Observation Due date	Date	Observation required due date
Observation Assigned to	CHAR(2)	Observation assigned auditor initial
Closed Date (Observation closed in Trackwise)	Date	Observation completed date