

# Michael Casner

Pitman, NJ - Email me on Indeed: [indeed.com/r/Michael-Casner/b78fccc1e2c7970d](https://indeed.com/r/Michael-Casner/b78fccc1e2c7970d)

Pharmaceutical Chemistry Research Professional with industrial and academic experience in process synthetic organic chemistry, bio-organic medicinal synthetic chemistry, technology planning, and technology assessment. Strong team player with excellent communication skills and a proven record of leading and coordinating project planning and implementation with business, analytical chemistry, process chemistry research, engineering, regulatory, and manufacturing groups.

## WORK EXPERIENCE

### **Contract Professor Organic Chemistry**

ROWAN UNIVERSITY, Department of Chemistry and Biochemistry - Glassboro, NJ - 2011 to 2013

Glassboro, NJ 2011 -2013

Temporary Assistant Professor, Rowan University, Department of Chemistry and Biochemistry, Instructor of Organic Chemistry, Industrial Organic Chemistry (for chemical engineer students), General Chemistry, and Advanced Chemistry I (accelerated general chemistry for engineers).

### **Principal Scientist, Senior Development Associate**

JOHNSON MATTHEY, Pharmaceutical Materials - West Deptford, NJ - 1998 to 2011

Synthetic Organic Process Chemist, Project Leader, & Supervisor

Solved environmental, safety, throughput, yield, capital investment, impurities, manufacturing troubleshooting, regulatory, and materials cost issues. Designed, developed, and demonstrated chemical processes from lab to manufacturing plant. Engaged in proactive process design, QbD.

- Increased production yield and quality specifications. Use of less expensive alternative materials triggered yield, impurity and distillation time problems. Designed a new extraction process that removed impurities and increased output, enabling Johnson Matthey to meet quality, regulatory and quantity goals for a key \$30M product.
- Designed process critical to generic drug manufacture. Production of a potentially profitable generic drug in the US and Europe by a Johnson Matthey subsidiary was blocked by process patents. Designed a synthetic process and associated HPLC method that avoided patent infringement while enabling launch of drug production.
- Solved research and impurity issues in raw materials, reference standards, and products.
- Developed in process analytical methods for process research: HPLC, NMR, TLC, IR, MS.
- Synthetic research projects include benzodiazepines, chiral resolution, calorimetry, gold drugs, homogeneous catalysis, monomers, nucleoside congeners, opiates, peptides, & phyloquinones.

### **Manager, Senior Research Chemist, Research Chemist**

Mallinckrodt Inc - St. Louis, MO - 1989 to 1997

Designed, developed, and demonstrated chemical processes from lab to pilot plant.

- Synthetic research projects include nucleoside derivatives, heterocyclic compounds (purines, pyrimidines, pyrroles), NSAIDs, solid phase peptide synthesis, Boc-amino acids.
- Evaluated new technology including organic synthetic methods (catalysts, processes towards target molecules), combinatorial chemistry and molecular design research, molecular modeling, and novel molecular entities (analgesics).
- Reviewed and assessed internal and external research and marketing proposals. Researched opioid and non-opioid analgesics, addiction therapy, peptide synthesis, generic drug synthesis, and drug delivery.

- Identified novel research to enable competitive advantage in generic drug manufacture.

### **Senior Chemist Process development**

MERCK & CO - Danville, PA - 1987 to 1989

manufacturing support and troubleshooting.

- Optimized process improvements to avoid capital investments for a  $\beta$ -lactam antibiotic.

#### **Skills**

- Expert in troubleshooting manufacturing problems, vendor qualification, and technology transfer. Investigated batch record implementation errors, off spec products, impurities in raw materials &/ or products, root cause analysis (RCA), corrective actions and preventative actions (CAPA), and process hazards analysis.
- Expert in proactive process design, QbD. Designed, developed, and demonstrated chemical processes from lab to pilot plant to large scale cGMP production. Lean sigma and operation excellence (OE) training.
- Expert in developing crystallization methods for drug intermediates and final products.
- Expert in synthetic process chemistry for target active pharmaceutical ingredients (API), key raw materials, and drug intermediates.
- Expert in enabling cGMP manufacturing regulatory filings, including DMFs, INDs, and (a)NDAs. Formal CE training in GCP: CRA CRC beginner program.
- NMR: Achieved upgrades for an NMR instrument (300 to 400 MHz). Lead its maintenance and troubleshooting. Solved research and impurity problems in raw materials and ref. standards.
- Developed in process analytical methods for process research: HPLC, NMR, GC, TLC, IR, MS.
- Determined polymorph status of drug candidates using XRD, DSC, TGA, and IR.
- Intellectual Property: Evaluated patents and literature to determine freedom to operate (FTO) synthetic processes for generic drugs. Database searching USPTO, EPO, WIPO, et al.
- Manager of Technology Planning: Identified, funded and monitored external research. Identified novel research to enable competitive advantage in generic drug manufacture. Reviewed and assessed internal and external research and marketing proposals.
- Trained, educated, and mentored colleagues on solving problems and to search for chemical information to support customer needs and regulatory issues.
- Taught Advanced Chemistry (accelerated general chemistry), Advanced Organic Chemistry, Medicinal Chemistry, Organic Chemistry, Spectral Methods, QSAR, drug design
- Wrote Grant applications: Synthesis of taurine ESR spin labeled probes for membrane studies.
- Community Leadership: Emergency First Responder; Taught self defense (Aikido) to Rowan U. students; Chair, Program Chair, Treasurer, Alternate Councilor and Science Fair Judge for the South Jersey American Chemical Society; Toastmasters International Area Governor.

#### **EDUCATION**

##### **PhD in Chemistry**

The University of Arizona - Tucson, AZ

##### **BSc in Pharmacy**

The University of Kansas - Lawrence, KS

#### **SKILLS**

- Expert in troubleshooting manufacturing problems, vendor qualification, and technology transfer. Investigated batch record implementation errors, off spec products, impurities in raw materials &/ or products, root cause analysis (RCA), corrective actions and preventative actions (CAPA), and process

hazards analysis. • Expert in proactive process design, QbD. Designed, developed, and demonstrated chemical processes from lab to pilot plant to large scale cGMP production. Lean sigma and operation excellence (OE) training. • NMR: Achieved upgrades for an NMR instrument (300 to 400 MHz). Lead its maintenance and troubleshooting. Solved research and impurity issues in raw materials and reference standards. • Developed in process analytical methods for process research: HPLC, NMR, GC, TLC, IR, MS. • Determined polymorph status of drug candidates using XRD, DSC, TGA, and IR. • Expert in developing crystallization methods for isolation of drug intermediates and final products. • Expert in synthetic process chemistry for target medicinals, key raw materials, and drug intermediates encompassing: amphetamines, benzodiazepines, Boc-amino acids, chiral resolution, calorimetry, drug conjugates, gold drugs, heterogeneous and homogeneous catalysis, heterocyclic compounds (purines, pyrimidines, pyrroles), , NSAIDs, nucleoside/ -tide congeners, opiates, peptides, phylloquinones, platinum drugs, solid phase peptide synthesis, and sugar derivatives. • Expert in enabling cGMP manufacturing regulatory filings, including DMFs, INDs, and (a)NDAs. Formal CE training in GCP: CRA CRC beginner program. • Intellectual Property: Evaluated patents and literature to determine freedom to operate (FTO) synthetic processes for generic drugs. • Expert in proactive process design, QbD. Designed, developed, and demonstrated chemical processes from lab to pilot plant to large scale cGMP production. • Manager of Technology Planning: Identified, funded and monitored external research. Identified novel research to enable competitive advantage in generic drug manufacture. Reviewed and assessed internal and external research and marketing proposals. • Trained, educated, and mentored colleagues on solving problems and how to search for chemical information to support customer needs and regulatory issues. Well versed in searching chemical, patent and drug databases: SciFinder, STN, CAS databases, CAlplus, Registry, USPTO, Orange Book, EPO, Micropatent, WIPO, and web based searching. • Designed and arranged collaborative interdisciplinary research. • Wrote Grant applications: Synthesis of taurine spin labels as ESR probes for membrane studies. • Taught Advanced Chemistry, Advanced Organic Chemistry, Medicinal Chemistry, Organic Chemistry, Spectral Methods, Advanced Med. Chem. (QSAR, drug design)

## LINKS

<http://www.linkedin.com/in/michaelcasner>