James J. Mencel, Ph.D.

Senior Drug Substance Consultant

Core Competencies

- Tech Transfer
- API/ Drug Substance
- Patent & Due Diligence
- Small Molecule
- Peptides & Peptidomimetic
- Risk Assessment
- API Synthesis Design
- Process Chemistry
- CMO Selection

Professional Summary

Dr. Mencel has served the pharmaceutical industry for over 36 years with practical experience in all aspects of synthetic chemistry and API development, as well as early drug product formulation. In this capacity, Jim is also technically proficient in several languages which serves his work with the global CMO community. As a DSI Subject Matter Expert, Jim assists our clients in providing timely technical assistance as both an author and an advisor.

Jim began his career in Discovery Chemistry and progressed to peptide and small molecule API chemical process R&D, with a focus on lab-to-plant transfer for GMP clinical supply and commercial manufacturing, and on inter-site technology transfer. This also includes API synthesis design and Phase 1 Formulation sourcing support for our clients. He influences and oversees projects ranging from pre-IND chemistry development to pre-launch validation commercialization and material sourcing for late-stage clinical trials. Jim has extensive expertise in technology transfer of chemistry from the research laboratory to kilo labs, pilot plants and contract research and manufacturing organizations. In this capacity, he has proven indispensable.

Dr. Mencel has served our Clients as a Subject Matter Expert for regulatory and patent input. This includes, but is not limited to, follow-up responses for regulatory and patent authorities as well as assisting in DSI authored regulatory filings. He is fluent in English (mothers' tongue), French, Spanish and is capable with technical German.

Education

Ph.D.	Organic Chemistry	Yale University
M.S.	Organic Chemistry	Yale University
B.S.	Chemistry	Fairfield University

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Professional Experience

Design Space Inpharmatics, LLC **2015 - Present**

Senior Drug Substance Consultant

Provides expert process chemist services with extensive experience in the development of practical syntheses for a wide range of APIs. Jim is a client advocate, applying principles of quality risk assessment and sound science to provide CMC guidance to all aspects of his area of drug substance.

Galleon Pharmaceuticals **2012-2015**

Director of Chemistry Manufacturing and Controls

Managed external chemical route, formulations and analytical development and GMP manufacturing for small molecule API's. Managed API and Drug Product regulatory strategy and position. Selected and managed API and Drug Product CRO's and CMO's. Prepared regulatory documents, IP strategy, drafting, and management. Provided CMC and IP budgetary tracking and forecasting.

Johnson Matthey Pharmaceutical Materials and Services **2006-2012**

Technical Fellow, Chemical and Analytical Development

Supported multisite chemical and analytical development. New Business Development program cost forecasting. Inter-site technology transfer. Synthetic route definition, development, and scale-up. Analytical methods development and validation. Plant implementation for cGMP process validation and commercialization. Provided commercial manufacturing support, legacy route cost improvement, intellectual property and regulatory strategy.

Rhodia Pharma Solutions **2000-2006**

Group Leader, Development Services, Process Chemistry Solutions

Managed multiple project teams to provide drug substances under cGMP (30–750 Gallon equipment). Technical and program leadership. Staff management. Customer liaison. Reviewed customer technology packages. Cost and resource forecasting for proposals. Management of project cGMP. Author project close-out reports to customers.

- Specialty areas: Small Molecule and Peptide Pharmaceuticals,
- Managed PR&D and cGMP manufacturing programs,
- Managed customer – scientist interactions, negotiate deliverables, cost forecasting,
- Lea inter-site technology transfer,
- Played a major role training colleagues in process scale-up and staff development.

Rhône-Poulenc Rorer **1987-2000**

Section Manager, Process Chemistry

Manage Discovery/Development chemistry interface. Assist Discovery during candidate selection. Project Team Process Chemistry Representative. Directly manage teams and key projects. Provide lab batches (25-500 g). Define IND route and transfer to plant (50-300 Gallon equipment). Negotiate quantities and timings. Select, develop, and industrialize NDA route. Manage preparative HPLC function. International/multilingual team leadership.

- Peptide and peptidomimetic API's,
- Managed Preparative HPLC services function,
- Led "Lab to Plant" IND transfer teams,
- Organized / coordinated multisite teams,
- Served as process patent liaison for Process Chemistry.

Trouble-shoot peptide production & purification. Propose, develop and implement industrial routes and process changes. Coordinate international teams to demonstrate and implement new manufacturing processes. Discovery Support Process Chemistry Liaison: Support peptide/peptidomimetics synthesis and HPLC purification. Supervise teams of scientists. Student intern manager.

- Started Peptide Chemistry Group
  - identified capital equipment, designed Collegeville, PA site peptide labs,
  - identified key hires,
  - established contacts with key internal customers and associates.
- Devised major improvements to Calcitonin solid–phase manufacturing process
  - demonstrated chemistries at 5% of production scale,
  - prepared transfer documentation.
- Provided peptide standards / peptide methods support for Discovery
  - scale-up and purify lead peptide API candidates,
  - instructed Discovery staff on peptide synthesis and purification.

Revlon Health Care Group R&D, **1984-1987**

Senior Chemist, Cardiovascular Diseases, Medicinal Chemistry

API route definition, process development and scale-up. Strategic drug regulatory and intellectual property planning. Customer negotiations and interactions. Cost forecasting. Discovery-Development interface and NCE profiling. cGMP manufacturing campaign management. Staff recruiting and development. Broad experience with student interns. Oral Presentation and Business Proposal expertise. Chemistry symposia management. Skilled at languages; capable in French and Spanish.

Awards:

1989: Rorer: Rorer Central Research Innovation Award
1993: RPR: Nominated, RPR Corporate Innovation Award for Science
1995: RPR: Supervisor of the Year Award, In-Roads Middle Atlantic Division
1996: RPR: Discovery Division Team Award for Klerval development contributions
2002: Rhodia ChiRex: Bonus award for excellence in performance

2003: Two formal customer commendations for excellence
2004: Rhodia Pharma Solutions Excellence Retention Bonus
2008: Johnson Matthey Corporate Innovation Award