James J. Mencel, Ph.D.

Head of Drug Substance Services

Core Competencies

- Tech Transfer
- API/ Drug Substance
- Patent & Due Diligence
- Small Molecule
- Peptides & Peptidomimetic
- API Regulatory Strategy
- 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. As a DSI Subject Matter Expert, Jim's strengths are development of chemical processes and controls in view of current ICH guidances, the authoring and review of regulatory documents, and technical oversite of GMP API manufacturing.

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 across clinical phases and eventual commercial manufacturing, and on inter-site technology transfer. This also includes API synthesis design and Phase 1 oral and parenteral formulations development. He influences and oversees projects ranging from pre-IND chemistry development, phase-appropriate chemical development, pre-launch validation, commercialization, and material sourcing for late-stage clinical trials. Jim has extensive expertise in managing process development and GMP manufacturing activities from kilo lab to industrial scale internally and via contract research and manufacturing organizations, domestically and overseas.

Dr. Mencel has served our clients as a Subject Matter Expert for development reports, manufacturing documents, DSI authored regulatory filings, and patent input. This includes, but is not limited to, follow-up responses for regulatory and patent authorities.

Summary of Experiences: API route definition, process development and scale-up across all clinical phases and commercial. Application of ICH guidances to technical development in view of regulatory filings and commercialization. Strategic drug regulatory and intellectual property planning and IP portfolio support. Inter-site technology transfer. Multinational. multicultural program leadership. Customer negotiations and interactions. Program Cost forecasting. Discovery-Development interface and NCE profiling. cGMP manufacturing campaign management. Chemistry symposia management. Skilled at languages; capable in French and Spanish; capable in translating written 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**

Head of Drug Substance Services

Provides expert process chemist services with extensive experience in the development of practical syntheses for a wide range of APIs with ICH principles in focus to support regulatory filings, process validation and commercialization. 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. Provided CMC budgetary tracking and forecasting and API cost of goods estimations. Commercialization 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 client project. Author project close-out reports to customers.

- Specialty areas: Small Molecule and Peptide Pharmaceuticals,
- Managed PR&D and cGMP manufacturing programs,
- Managed multisite PR&D and cGMP manufacturing programs,
- Managed customer – scientist interactions, negotiate deliverables, cost forecasting,
- 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,
- 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 and Hypersensitivity Diseases, Medicinal Chemistry

Design and synthesize target molecules. Interact with supporting Discovery disciplines. Serve on cardiovascular diseases area team and managed laboratory staff.

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