



John C Amedio, Ph.D.

Summary. Pharmaceutical executive with broad expertise in technical and regulatory CMC development of small molecules and peptides from the bench to the market. Areas include:

- Process R&D/validation
- Formulation Development
- cGMP Manufacture
- Solid/Injectable dose form development
- Analytical Method Development
- CMO sourcing/management
- Packaging/labeling
- CMC Regulatory Strategy, IND/NDA Filing

Professional Experience

Amedio CMC Consulting
Principal: 2013-present

Seaside Therapeutics
Vice President, Manufacturing & Process Development: 2009-2013

ZIOPHARM Oncology, Inc.
Vice President, Manufacturing & Process Development: 2006-2009

EPIX Pharmaceuticals
Executive Director, Chemical and Analytical R&D: 1995-2006

Sandoz Research Institute (US and Switzerland)
Unit Head, Chemical Development: 1989-1995

Education/Certification

1982; BS, Manhattan College

1987; PhD, University of Delaware

1987-89; Post-doctoral, Oregon State University

Drug Development Experience

- Managed worldwide CMC development programs for multiple API's and drug products
- Delivered profitable and patented manufacturing processes (API and finished drug product, injectable and oral dosage forms; capsules, tablets and orally disintegrating tablets) for Arbaclofen, Zinapar™, Zibulin™, Zymafos™, Vasovist™ (currently Ablavar®), multiple NCE's, including peptides and metal-based drugs (pre-clinical through commercial)
- Authored and reviewed CMC sections for multiple regulatory filings (INDs, Amendments, Annual Updates, Briefing Books and an NDA; IMPD documentation to EMA and Canadian authorities)
- Extensive knowledge in primary/packaging, labeling and supply chain/distribution activities

Selected Publications/Patents

- Jones, B.; Komarnitsky, P.; Miller, G.; Amedio, J. and Wallner, B.P. *Anticancer activity of stabilized palifosfamide in-vivo: schedule effects, oral bioavailability and enhanced activity with docetaxel and doxorubicin*, *Anti-Cancer Drugs*, 2012, 23(2), 173-84.
- Levy, S.G.; Zhou, K.L.; Jacques, V.; Kalogeropoulos, S.; Schumacher, K.; Amedio, J.C. Jr.; Scherer, J.E.; Witowski, S.; Lombardy, R. and Koppetsch, K. *Development of a Multigram Asymmetric Synthesis of 2-(R)-2-(4,7,10-Tris tert-Butylcarboxymethyl-1,4,7,10-tetraazacyclododec-1-yl)-pentanedioic Acid, 1-tert-Butyl Ester, (R)-tert-Bu4-DOTAGA*, *Organic Process Research and Development*, 2009, 13(3), 535.
- Caravan, P.; Amedio, J.C. Jr.; Ellison, J. J.; Cloutier, N.C.; McDermid, S. A.; Spiller, M.; Zech, S.; Looby, R. L.; Raitsimring, A. M.; McMurry, T. J. and Lauffer, R. B. *When are two waters worse than one? A novel gadolinium(III) complex based on N-methyl-diethylenetriametetraacetate*, *Chem. Eur. J.* 2005, 11, 5866.
- Prashad, M.; Amedio, J.C., Jr.; Ciszewski, L.; Lee, G.; Villa, C.; Chen, K-M.; Prasad, K. and Repic, O. *Practical Synthesis of 3-Carboxy-(2R)-[[hydroxy[(tetradecyl)oxy]-N,N,N-trimethyl-1-propanaminium Hydroxide Inner Salt (CPI975): A Carnitine Palmitoyltransferase I Inhibitor.*, *Organic Process Research and Development*, 2002, 6(6), 773.
- Caravan, P.; Cloutier, N.; Greenfield, M.T.; McMurry, T.J.; McDermid, S.A.; Dunham, S.U.; Bulte, J.W.M.; Amedio, J.C.; Looby, R.J.; Lessman, J.J.; Supkowski, R.M.; Horrocks, W. DeW. and Lauffer, R.B. *The interaction of MS-325 with human serum albumin and its effect on proton relaxation rates*, *J. Am. Chem. Soc.*, 2002, 124(12), 3152.
- Amedio, J.C., Jr.; Van Wagenen, G.; Zavlin, G. *Preparation of N,N-Bis[2-[N',N'-bis(tert-butoxycarbonyl)methyl]-amino]ethyl-L-aspartic acid: An Intermediate in the Synthesis of MRI Contrast Agents*, *Synth. Commun.*, 2000, 30(20), 3755.
- Amedio, J.C., Jr.; Bernard, P.; Fountain, M.; Van Wagenen, G., *A Practical Manufacturing Synthesis of 1-(R)-Hydroxymethyl-DTPA: An Important Intermediate in the Synthesis of MS-325*, *Synth. Commun.*, 1999, 29(14), 2377.
- Amedio, J.C., Jr.; Bernard, P.; Fountain, M.; Van Wagenen, G., *A Practical Preparation of 4,4-Diphenylcyclohexanol: A Key Intermediate in the Synthesis of MS-325*, *Synth. Commun.*, 1998, 28 (20), 3895.
- White, J.D.; Amedio, J.C., Jr.; Hrcniar, P.; Ohira, S.; Lee, N.C.; Ohira, S.; Yokochi, A.F.T., *Asymmetric Synthesis of Dimethyl Swazinecate and Structural Confirmation of its Parent Alkaloid (-)-Swazine*, *Chem. Comm.* 1998, (5), 603.
- Amedio, J.C., Jr.; Lee, G.T.; Prasad, K.; Repic, O., *A Practical Preparation of Methyl 4-(trimethylsilyl)benzoate: An Intermediate In The Synthesis of SDZ63135*, *Synth. Commun.*, 1995, 25(17), 2599.
- Amedio, J.C. Jr.; Sunay, U. B.; Repic, O., *Metalated Carboxylic Acids: Improved Synthesis of SDZ 62-412*, *Synth. Commun.*, 1995, 25(5), 667.
- Lee, G.T.; Amedio, J.C., Jr.; Underwood, R.; Prasad, K.; Repic, O., *Vinylformylation Utilizing Propeniminium Salts*, *J. Org. Chem.* 1992, 57, 3250.
- White, J.D.; Amedio, J.C., Jr.; Gut, S., Ohira, S.; Jayasinghe, L.R., *Stereoselective Synthesis of the Pyrrolizidine Alkaloids (-)-Integerrimine and (+)-Usaramine*, *J. Org. Chem.* 1992, 57, 2270.
- *Optically pure and enriched isomers of chelating ligands and contrast agents*, US Patent 8,048,906
- *Peptide-based multimeric targeted contrast agents*, US Patent 7,927,581
- *Targeting multimeric imaging agents through multilocus binding*, US Patent 6,652,835
- *Process for synthesizing phosphodisesters*, US Patent 5,919,967
- *Process for preparing 1,4,8,11-tetraazacyclotetradecane*, US Patent 5,608,061

Professional Activities

- American Chemical Society (ACS)
- American Association for the Advancement of Science (AAAS)
- American Association of Pharmaceutical Scientists (AAPS)
- Parenteral Drug Association (PDA)