Meet the Expert

Jeff is considered an expert and contributor to the design, construction, commissioning and qualification of state-of-the-art manufacturing facilities producing key biopharmaceutical therapeutics and vaccines in the global marketplace. He is sought after for his knowledge of Facility of the Future/NextGen manufacturing methodologies.

For more than 27 years, Jeff has assisted biopharmaceutical manufacturers managing the design and construction of many of the industry's major manufacturing projects, as well as compliance and strategic consulting roles for a number of the global biotechnology industry leaders. These projects represent a total capital investment of well over $2 billion dollars and produce many of the key biopharmaceutical therapeutics and vaccines currently in the global marketplace. Jeff has conducted facility compliance and quality systems audits and has participated in the development and presentation of licensing packages to FDA. He has provided cGMP audit services and training for Fortune 500 global biopharmaceutical companies, focusing on FDA and EU compliance as part of inspection readiness and for FDA and other global regulators.

Jeff is a nationally recognized speaker providing industry insight in the areas of regulatory compliance, process design and project management for biopharmaceutical companies. As the former Technical Advisor to ISPE, Jeff assisted in the development and execution of international training projects specific to the manufacture of biologics and pharmaceuticals. He currently leads several professional industry training courses both nationally and internationally and is the recipient of the Society's prestigious Richard B. Purdy Award for Outstanding Achievement. Jeff is a Teaching Fellow at North Carolina State University's BTEC Graduate Program in Biomanufacturing and has developed numerous training programs for professionals in the US and 15 other countries around the world.

Jeff completed a well-received three-part series focused on defining the Facility of the Future (FoF) required for biomanufacturing in the 21st century. He is the author of more than 65 published works on many critical industry topics. These works include 6 books which are recognized industry reference guides, including *Sterile Product Facility Design and Project Management*. He has contributed as chapter author for numerous *Baseline Pharmaceutical Engineering Guides* and also to the *Encyclopedia of Industrial Biotechnology.*

In addition, Jeff leads the IPS Technologies Tours, conducted during a major biopharmaceutical industry tradeshow, featuring Biomanufacturing Technologies. The Tour includes visits to leading biotech suppliers to discuss new technologies, innovation and new strategies.

Jeff Odum, CPIP
Biomanufacturing Expert

jodum@ipsdb.com
888.366.7660

Areas of Expertise

- Biomanufacturing Facility Design
- Facility of the Future
- Aseptic Facility Design
- Compliance Auditing and Training
- Project Risk Analysis
- Technical Consultancy
- Process Improvement
- Facility Integration
- Process Architecture