

Tim Chalmers
Principal Consultant

Mr. Chalmers, Principal Consultant and Co-founder of Pharma Technology Resources, is a pharmaceutical industry professional with a strong background in manufacturing engineering services and manufacturing regulatory compliance. In his consulting practice, he has been a key provider of turnkey pharmaceutical engineering services, providing leadership on design, installation, validation, and training for complex manufacturing systems. His focus in manufacturing regulatory compliance has been the preparation and assessment of operating procedures and documentation, and preparation for production launch. He has held engineering positions in equipment design with Shaklee Corporation, a large cosmetic and food supplements company, and in manufacturing engineering with Syntex Laboratories, a major pharmaceutical company.

- Mr. Chalmers has produced FDA compliant standard operating procedures, specifications, and maintenance and manufacturing record keeping systems. These activities include assessment of current standard operating procedures and their associated documents, and implementation of procedural upgrades. Clients for these services have included established major pharmaceutical companies enhancing their regulatory compliance programs as well as for smaller companies whose operations were first entering FDA-regulated manufacturing.
- Mr. Chalmers' compliance activities have also included providing services as validation project manager and for the preparation of validation protocols. He has been responsible for preparing and conducting the validation of cleaning processes, processing and packaging equipment, and utility services. His validation project management activities have included the validation of a complex, FDA-compliant computerized document management system.
- As a pharmaceutical-manufacturing engineer, with a comprehensive background in turnkey pharmaceutical engineering projects, he has provided technical expertise for both single machine implementation and complex-line system integration. He has focused on the selection, justification, installation, validation and implementation of packaging and processing equipment. He has provided systems for the containment and control of high-potency pharmaceutical formulations and specified and implemented Clean-in-Place systems. Mr. Chalmers has also provided technical expertise in the design of equipment, cleaning processes, and SOP's to facilitate cleaning validation.
- As a project manager, he has extensive experience in all phases of manufacturing automation needs, equipment space planning, design ergonomics, facility and utility construction requirements, equipment and facility clean-ability, and the overall equipment investment requirements for pharmaceutical manufacturing projects. Mr. Chalmers has provided skilled leadership to address the key issues of personnel training, deployment and interaction with equipment as part of machine/line integration.

Mr. Chalmers is a skilled user of computer aided design (CAD) and project management software packages.