



## Commissioning, Qualification and Validation Master Planning (CVMP)

**When it comes to compliance, there is no substitute for experience. Over the past 20 years, we have executed large- and small-scale compliance-driven projects for over 500 of the world's leading pharmaceutical and biotechnology companies.**

Our strong client base and recent major compliance clients include:

- Adhesives Research
- Aptuit
- Bristol-Myers Squibb\*
- Cephalon, Inc.\*
- Celgene
- Charles River Labs\*
- Elan
- Eli Lilly & Co.\*
- Genitope Corporation
- GlaxoSmithKline\*
- Johnson & Johnson Family of Companies\*
- Matheson TriGas
- Merck & Co.\*
- Nabi Bio Pharmaceuticals
- Orthovita\*
- Pfizer\*
- Sanofi-Aventis / Sanofi-Pasteur
- Schering-Plough\*
- Schott Pharmaceutical Systems
- Shire Human Genetic Therapies
- Teva
- Wyeth\*

\* Multiple Project Sites

*Bolded items indicate Master Planning was included in the scope of work.*

IPS offers a full-range of comprehensive compliance consulting and audits, design reviews, commissioning, qualification and validation services, from initial project definition through customized project-specific needs. Our services are both bundled with our Design/Build projects and stand-alone as an independent compliance service provider.

Our compliance team is comprised of over 50 in-house professionals who provide compliance consulting and audits, design reviews, commissioning, qualification and validation services. With years of experience, they offer strategic compliance and operational support – effectively supporting and augmenting clients with IPS technical expertise.

### **Streamlining the Engineering and Compliance Process**

With the FDA moving towards a “risk-based” methodology and greater industry acceptance of integrated commissioning and validation efforts, we developed a formal program and practices for implementing a science- and risk-based validation program. Our approach aligns with current ISPE C&Q guidelines, ASTM E2500 and ICH standards. This approach simplifies qualification protocols and only focuses on areas of risk to product. The benefits to our clients by utilizing this approach are a shortened validation schedule, streamlined review process with auditors, enhanced lifecycle maintenance/management and sound change control, PM, and calibration programs.

### **The Strength of Experience**

IPS has helped many clients implement current industry methodologies through the development of Commissioning, Qualification and Validation Master Plans (CVMPs). CVMPs provide a well-organized foundation for directing and managing compliance efforts for projects. IPS' master plans typically provide a project overview, define objectives and project scope, define the roles and responsibilities of the project team, provide a project description, establish an integrated commissioning, qualification and validation approach, provide guidelines for IQ, OQ, and PQ, protocol content and testing, define protocol procedures and format requirements, reference support programs and establish a milestone schedule of activities. As the name implies, master plans add the most value when used as a planning tool. Early development of the master plan allows for early agreement on the approach by the entire project team and upper management. When an integrated approach is utilized, FAT/SAT activities, vendor start-up, and vendor commissioning can be determined and purchased during the equipment and contractor procurement phase of the project (more competitive prices).