Welcome

Providing Superior Consulting Services to Pharmaceutical, Biotechnology and Medical Device Firms

April 25, 2009

"Celebrating our 2nd Decade of Exceeding our Customer Expectations…"

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Company Overview

- Validation Plus has been providing a full spectrum of compliance consulting services to the Pharmaceutical, Biotechnology and Medical Device Industries since 1995
- The services of Validation Plus, Inc. include: All phases, from concept design to FDA approval

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The Validation Plus Advantage

Our Goal: To exceed your expectations

How Do We Do It?

- We listen and learn what your goals are
- We ask YOU what would exceed YOUR expectations
- We provide you with senior and principal consultants (senior consultants have 10+ years experience, principals have 20+ years experience)
- We custom select the best people (to exceed your expectations)
- We provide project management Plus executive management (executive management assures that potential problems are resolved BEFORE they can affect your project)

Result: We have received over 20 letters of recommendation!

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Facility Design, Commissioning, and Validation Services

Providing a full range of facility design, commissioning and Validation Services including:

- Conceptual Design
- Architectural and Facility Design Services
- GMP Design Review
- Equipment Recommendations
- Purchasing Requirements
- Construction
- Factory and Site Acceptance Testing
- On-Site Commissioning and Startup
- Calibration
- Validation
- Project Close-Out

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The Validation Plus Advantage: Experience

- Our experience comes from working for leading pharmaceutical, biotechnology and medical device firms for over 13 years
- Each Validation Plus senior consultant has “hands on” experience with multiple validation services and systems, in addition to both education and practical experience in their field of validation
- *Our people include:* designers, architects, and engineers spanning the spectrum from receiving to shipping, in production, quality assurance, calibration, validation, regulatory affairs, information technology, and ex-FDA representatives

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The Validation Plus Advantage: Knowledge

Knowledge to facilitate the success of a project…

- Validation Plus provides guidance documents
  - Requirements for Successful Validation
  - How to Build Quality Into Commissioning and Validation
- Validation Plus has performed numerous projects – they are experts who know what needs to be done, and when, and how

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The Validation Plus Advantage: Consistency

Consistency To facilitate the success of a project…

- The Validation Plus senior consultant remains on the project from inception through completion
- This promotes better communication to meet our client's validation needs
- Validation Plus recommends smart, cost-effective solutions that save our clients time and money and solve their problems

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Management Team

Jeffrey Gassman

- President (and founder) of Validation Plus
- Chemical Engineer with 20+ years of validation experience
- Validation projects performed include Stryker Orthopedics, Olympus America, Sanofi-Aventis, Wyeth, Bristol Myers-Squibb. Pfizer, Warner-Lambert, Bayer, Schering-Plough, Hoffmann-La Roche, and Chiron

Dr. Richard Prince

- Executive Vice President of Business Development
- 20+ years of industry experience with expertise in Quality, Compliance, Business Development, and Microbiology
- Extensive management experience (he has held positions of General Manager, and Director prior to joining VPI)
- Dr. Prince has published several books on Microbiology

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Examples: Delivery

Delivery To facilitate the success of a project…

- Commissioned and validated two facilities - Chiron
- Designed, commissioned, and validated facility - ImmunoGen
- Commissioned and validated a $50 million dollar Multi-Product Cell Culture and Protein Purification Facility. - Hoffmann-La Roche
- Commissioned the Purification Area (one floor) of a $125 million dollar Multi-Production Biotechnology Facility. (3 floor facility) - Bayer
- Turn-key project - Fox Pharmaceuticals
- Conceptual design, GMP design review – Morphotek

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Examples: Delivery (cont.)

Delivery To facilitate the success of a project…

- Turn-key project in Irvine, CA (confidential client)
- Dozens of computer validation projects
- Performed 300+ CGMP compliance and vendor audits nationally and internationally.
- Dozens of equipment validations including refrigerators, lyophilizers, freezers, autoclaves, depyrogenation ovens, filling lines, bioreactors, and purification equipment.
- Dozens of facility and utility projects including HVAC, BMS, clean steam, WFI, RO/DI water, compressed air, and N2.

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Client Testimonials

"Jeffrey Gassman worked under my direction as a Quality Assurance Consultant and his responsibilities included an independent review of equipment and utility systems qualification reports and developing a validation plan with estimated resource requirements for IT validation of medical complaint handling, secured file transfer of clinical information and LAN validation.

Utilizing his experience, he was able to provide timely review with sufficient detail that allowed several departments to improve the draft qualification documents. His contribution by developing an IT validation plan allowed for determining what resources were needed to develop a complete quality system and SOPs for validation of automated systems."

-New England-Based Biotech Company

"I found the Validation Plus personnel worked well with our internal and consulting personnel and made numerous constructive suggestions to enhance the program. I considered them experts in their field and relied on their advice in troubleshooting the process issues encountered during the execution phase. All Validation Plus personnel working on the project were hard working individuals who took the project very seriously to compete on schedule and on budget.

They produced quality protocols and reports meeting our expectations. All personnel were courteous and professional and I have no hesitation to recommend Validation Plus to you."

-Fortune 50 Pharmaceutical Company

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Customers

Our goal has resulted in numerous letters of recommendation from pharmaceutical, medical device, and biotechnology firms including:

Abbott Laboratories

Eisai

Wyeth

Bristol-Myers Squibb Company

Aventis

OLYMPUS

Bayer

Pfizer

Schering-Plough

Centocor

VALIDATION MASTERS

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Contact Us

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