



PROPHARMA GROUP NEWS

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ProPharma Group

has reached the 5 year milestone. We thank all of you —clients and employees— for your trust and opportunities over the years. We have doubled in size each of the past 5 years. This has been possible only because of our loyal clients and committed employees.

We are continuing our plans to grow the company in a methodical manner to increase our range of services and deepen our strength in all areas of commissioning, qualification and validation. While we continue to widen our range of services, we remain focused on providing high-value services that put the most talented validation professionals in the industry in your plant and bring your projects in on-time, in-budget and in compliance.

Jeff Hargroves
President

PROPHARMA GROUP OPENS SAN FRANCISCO OFFICE AND INTRODUCES CHARLES JABARA AS SENIOR MANAGER OF THE WEST COAST REGION



Earlier in 2006 ProPharma Group opened a San Francisco office to serve its' clients on the West Coast. Charles Jabara is being introduced as Senior Manager, West Coast Region. ProPharma Group's continued growth can be attributed to the organization holding true to its' core principles of Experience, Integrity and Commitment. These principles assist their clients in ensuring that projects are In-Budget, On-Time and In-Compliance.

Mr. Jabara is a Certified Black Belt in Lean/Six Sigma as well as a Certified Project Manager with over 10 years experience in practice. Mr. Jabara's diverse background includes conceptual

and detailed design of facilities and equipment, the validation of facilities, utilities, process equipment, cleaning and manufacturing processes.

Mr. Jabara has worked with a variety of organizations managing multi-million dollar projects, production, engineering, and maintenance departments. He is recognized as an expert in full cycle project planning and implementation and enjoys the ability to work closely with business clients and technology personnel during the design, configuration, application and training stages of any given project.

USP/NF 2006 2ND SUPPLEMENT— MICROBIOLOGICAL TESTS

Written By: Dave Koczan—Aperio Scientific

The USP recently published the 2nd Supplement to the USP/NF 2006 compendia. There are numerous changes and new guidelines that will be implemented in the coming year which will impact the Microbiology lab.

The Microbial Limits Chapter <61> has been replaced by two new chapters. Chapter <61> “Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests” provides guidance for performing quantitative determinations for bacteria and yeast & molds. The new chapter discusses the suitability of different counting methods based on the type of product tested. The chapter also includes a table of common neutralizing agents which can be employed to neutralize the activity of antimicrobial agents in product formulations. Four methods are described for the enumeration of microorganisms in product:

- ▶ Membrane filtration
- ▶ Pour-plate method
- ▶ Surface-spread method
- ▶ Most Probable Number (MPN)

The membrane filtration and plate methods provide better accuracy and precision than the MPN procedure and the MPN procedure should only be performed for the Total Aerobic Microbial Count (TAMC) if no other suitable method is available. The chapter also provides a section on interpretation of results. When an acceptance criterion for microbiological quality is prescribed, it is interpreted as follows:

- ▶ 101 cfu: maximum acceptable count=20
- ▶ 102 cfu: maximum acceptable count=200
- ▶ 103 cfu: maximum acceptable count=2000; and so forth.

The acceptance criteria for different product classifications is described in the newly revised General Information Chapter <1111> “Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use.”

Chapter <62> “Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms” is derived from the original Chapter <61> “Microbial Limit Tests”. Several modifications and changes have been implemented for the detection of objectionable microorganisms. The first change is the use of Soybean Casein Digest Broth as the primary broth culture media, replacing Lactose Broth in the E. coli and Salmonella tests. Additional modifications to these tests provide different enrichment media and fewer selective media for subculture. The chapter also includes two new procedures for the detection of Bile-Tolerant Gram Negative Bacteria and a culture procedure for the detection of Clostridia. Acceptance criteria for the absence of particular objectionable microorganisms based on product classification can be found in Chapter <1111> “Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use.”

EXPERIENCE
PROPHARMA GROUP HAS INTEGRITY
COMMITMENT



GETTING TO KNOW THE PROPHARMA GROUP STAFF



Ms. Patti Korando is a technical manager with 15 years of experience in pharmaceutical development and manufacturing,

and a Master Blackbelt in Six Sigma. She is experienced with validation of analytical and process equipment. Patricia has managed technical transfer and validation projects for active pharmaceutical ingredients, and parenteral manufacturing processes. She has developed quality systems for laboratory operations and production facilities. Her managerial experience includes staffing, budgeting, project planning and oversight.

Ms. Korando graduated from Washington University with a Master of Business Administration, Manufacturing Management. She also earned a Bachelor of Arts, Major in Physical Anthropology. She also is certified in Lean Manufacturing from the University of Kentucky and ISO 9000 Lead Auditor from Bywater, Inc.

Mr. Greg Spanel is joining ProPharma group after spending 9 years working in the Pharmaceutical/Biotech industry. His experience

includes the management, execution and development of commissioning and qualification programs at new and existing active pharmaceutical ingredient, finished pharmaceutical and biopharmaceutical facilities. He is also experienced in project management, project engineering, process engineering, auditing, quality assurance, change control, training, statistical process controls, cleaning validation and process validation.

Mr. Spanel is an active member of ISPE. He is currently serving as the Vice President of the Midwest Chapter and a member of their Board of Directors.

Mr. Spanel graduated from Iowa State University with a B.S. in Chemical Engineering. He has also earned an M.B.A in Business Management from Webster University. Mr. Spanel holds certifications as a Project Management Professional (PMP) from the Project Management Institute as well as a Training Generalist from Langevin Learning Services.

ProPharma Group and Marion Weinreb & Associates

Co-exhibitors at two Annual Events

ProPharma Group & Marion Weinreb & Associates will be located in Booth #429 at the upcoming Regulatory Affairs Professionals Society (RAPS) Annual Meeting that will take place in Baltimore, Maryland on October 16 & 17. The two companies also exhibited at the Society of Quality Assurance (SQA) Annual Meeting located in Phoenix, Arizona on April 25 & 26th.

ProPharma Group, Inc. (PPG) and Marion Weinreb & Associates, Inc. (MWA) have been strategically aligned since August 2005 to offer comprehensive GXP compliance services to pharmaceutical, medical device and biotech companies. This alliance maximizes the core capabilities of each company, which currently offer synergistic compliance and validation services to their clients.

DO YOU HAVE A FRIEND OR FAMILY MEMBER IN THE JOB MARKET?

ProPharma Group is searching for professionals experienced in equipment, process, facility, computer and cleaning validation.

If you know someone that might be interested in learning more about ProPharma Group and career opportunities please have them visit our website at: www.propharmagroup.com or contact Jenny Hicks (913) 661-1662.



PROPHARMA GROUP IS LOOKING FORWARD TO THE FOLLOWING CONFERENCES AND EVENTS:

ISPE Midwest Chapter—Golf Outing & Educational Program
Springfield, Missouri—October 9

Regulatory Affairs Professional Society (RAPS)—Annual Meeting
Baltimore, Maryland—October 16 & 17
Booth # 429

National Institute of Health (NIH) Festival
Bethesda, MD—October 19 & 20

ISPE Annual Event
Orlando, Florida—November 5, 6 & 7

2007
Interphex
New York, New York—April 24, 25 & 26
Booth # 1982

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