2015

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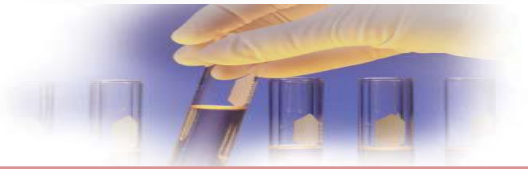

Modern Approach of Pharmaceutical Solids Formulation & Process Development

Develop solid understanding of:

- Pharmaceutical Formulation
- Optimization and Process development
- Scaling Up
- Latest Technologies
- Practical problem solving
- Troubleshooting
- Process Validation

Holiday Inn

Montreal

May 21-22, 2015

Holiday Inn Pointe Claire

6700 TransCanada , Pointe Claire, Québec, H9R 1C2 **T. (514) 697-7110**

WWW.PROGAMMA.CA

Space is Limited
Act Today!

Course Objectives

Stay Current

The pharmaceutical industry need for formulation development support is ever increasing. With fewer new chemical entities every year, pharmaceutical reformulation is intense. By staying current with the latest good practices and new advances you help ensure your organization competitiveness. This new intensive 2-day course is designed to provide modern pharmaceutical state of the art information and techniques to participant and the chance to catch up with the latest developments in tablet technology, also with the new trends like QbD approach to new product development. Practical problem solving sections are inserted in each relevant subject to relate to everyday technical life experiences.

Who will Benefit?

Quality Assurance
Product/Process Development
Process Control
Technical services
R & D
Production
Analytical Development/Sciences
Research/Compliance Auditing
Validation Engineers

This course is also of interest to Equipment Contractors, Consultants and contract research organizations that specializes in Process Validation.

Why you should attend?

1. Learn from recognized experts and share with you their insights and knowledge of recent advances in modern formulation development
2. Learn about new trends formulation design - QbD
3. Learn how to integrate basic principals and current industrial practices of tablet technology
4. Learn state of the art technologies and cost-effective approaches
5. Get in good understanding of Wet and dry granulation
6. Increase and establish sound understanding of excipients and their role in drug formulation
7. Examine and learn about equipment selection and scale up
8. Develop a good understanding of how unit operation affect formulation
9. Establish solid understanding of choosing the right unit operation
10. Develop new skills of formulation design for poorly water soluble drugs

Distinguished Speakers

Ady Sadek, M.Sc., P.Chem, President of proGamma Science Corporation

previously he spent 25 years in the pharmaceutical industry with BioResearch, Schering-Plough and Novartis Pharmaceuticals, holding positions such as Manager of Analytical & Development Labs, Director of Quality and Director of Quality Audit. He holds two master degrees in Organic and analytical chemistry. Mr. Sadek's vast experience in process design and validation started in 1981, when developing new formulations for FDA submissions. He has been involved in many validations and his experience extends from formulation development to scale up commercial batches and technology transfer. He has consulted and lectured throughout Canada, USA and Europe to several multinationals.

Mihaela Pop, Ph.D. Chief Scientific Officer of TeraCrystal, Romania

Dr.Pop has a vast experience in the solid-state, accumulated from both academic and pharmaceutical industry working environments. Prior to TeraCrystal, Dr. Pop has led the Pharma team at Avantium BV, pioneer in the field of crystallization and polymorphism. Dr. Pop has a track record of innovation, being author and co-author of many patents and scientific publications in crystal engineering and crystal structure determinations. Dr. Pop holds a Ph.D. in Solid-State from "Babes-Bolyai" University of Cluj, Romania and a postdoctoral fellowship in Crystallography from University of Amsterdam, The Netherlands.

Piotr Bryla , Ph.D. President of Bryla CMC-Reg Consulting, LLC, USA

Dr. Bryla has 20-plus years of experience in developing drug substances and drug products in small, medium, and large pharmaceutical and biotech companies using internal resources and external contract organizations located worldwide. Dr. Bryla held positions of increasing responsibility including vice president of manufacturing and process development at Lux Biosciences and other senior management positions at Omeros Corporation, Barrier Therapeutics, Forest Laboratory, Bayer Corporation and Hoffmann -LaRoche. His expertise encompasses discovery, preformulation, formulation, analytical and manufacturing process development, clinical supply chain management, and preparation of CMC modules for clinical and marketing dossier applications. Dr. Bryla received his Ph.D. in Pharmaceutical Sciences and MS in Pharmacy and Pharmaceutical Analysis at the Academy of Medicine in Poland and completed his post-doctoral fellowship in the Pharmaceutical Chemistry Department at Rutgers University. He is a certified member of the Worldwide Who's Who Professional Organization.

Day 1

8:30 Registration – Continental Breakfast

9:00 am Pharmaceutical and formulation considerations for dosage form design

I. Preformulation Science in Drug Development

- Preformulation in Discovery and Clinical Developmental Phase
- Definition
- Regulatory aspect (QbR)
- General introduction to polymorphism, crystal habits and morphology, salt and excipient selection, stability, solubility and other solid characterization elements
- Impact on drug development (important decision to make), formulation, process ability and upscale

II. Practical Application of Solid State Chemistry

- Polymorphism; Solubility; processibility and stability
  - Crystal forms and amorphous phase: Definitions
  - Solid form screening (workflow)
  - Amorphous solid dispersions (workflow)
  - Solid form evaluation criteria and selection
  - Co-crystals (case studies)
- Compatibility study through binary mixture
  - Study of powder blends and binary compacts
  - Excipient induced disproportionation of salts
- Physical/chemical characterization
  - Techniques used for drug substances and drug products
  - Polymorphic purity determination
  - Salt or co-crystal? (case study)

Formulation & Process development

- Formulation development strategy
- Selection of equipment & process
- Selection of excipients & their impact on stability
- Impact on bioavailability
- Method development
- Evaluation of formulation robustness
- Foresee the regulatory hurdles
- Selection of primary packaging components & improved stability

Excipient Considerations

- Original concept
- Modern Concept
- Desirable characteristics of excipients

Implementation of Quality by Design in New Product Development

- What is quality by design
- ICH Q 8 , 9 and 10 require use of QbD in all development projects
- Optimum approach to QbD
- Design Space and tools
- Change management approach

4:30 pm End of day 1

Day 2

9:00 Scale-Up & Optimization Strategy

- Process & equipment selection
- Evaluation of product quality attributes
- Comparability study
- FDA suggested stratified sampling & blend uniformity
- Potential SUPAC & PAT related issues
- Identifying stability problems and establishing an appropriate stability program
- Analytical method validation

Tablet Lubricants

- Types
- Behavior and defects of lubricants

Manufacturing Unit Operation Effects on Solids Formulation

- **Dry Granulation**
  - Why choose dry granulation?
  - Advantages and disadvantages
  - Dry Granulation by slugging
  - Roller compaction
  - Factors affecting the compatibility of different materials
  - Comparison of wet and dry granulation.
  - Troubleshooting
- **Wet granulation**
  - Utility of Granulation
  - Advantages and disadvantages
  - End point detection
  - Factors to consider for wet granulation
  - Modern approach of wet granulation
  - Troubleshooting
- **Tablet Coating**
  - Principles
  - Types of coating
  - Advantages and disadvantages
  - Troubleshooting
  - Sugar coating
  - Film coating
  - Functional and non-functional coating e.g. Enteric Coating

Encapsulation

- Manufacture of Soft-shell & Hard-shell Capsules
- Principles and Equipment Utilized in Encapsulation

Change Control

- Important Element of a Change control system
- Who is responsible?
- Implications

4:30 End of day 2

proGamma Science Corporation

Registration Form

Modern Approach of Pharmaceutical Solids Formulation and Process development

Montreal .Canada May 21-22, 2015 ☐

Please return the completed registration form to:

By Mail: **By Fax:** (514) 697- 4355 **By Phone:** (514) 695-8622 **Email:** infoteck@progamma.ca

proGamma Science Corporation
6600 TransCanada, Suite 452,
Pointe Claire, Quebec, Canada H9R 4S2

Please Register the :

Name: **CAD $890.00**

Delegate (1):_____
Delegate (2):_____
Delegate (3):_____
Delegate (4):_____
Delegate (5):_____ FREE

SUBTOTAL $ _____
GST 5% _____
PST 9.95% _____
Total: $ _____

Name: _____
Company : _____
Address : _____
City: _____ **State / Province:** _____ **Postal code / Zip :** _____
Telephone : ( ) _____ Fax : ( ) _____E-mail:_____
Signature: _____

Method of Payment:

Payment endorsed , check is payable to : proGamma Science Corporation

☐ **Please invoice my company for the amount of $ _____ and our PO# is____ _____**

Please charge my credit card: **Please Fax this form if you are paying with credit card**

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Card Type: _____

Card Number : _____ **Expiry Date :**_____

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Authorization #
Date:

Venue: Holiday Inn Pointe Claire , Pointe Claire , Montreal , Quebec
Registration fee: $890.00 , includes the presentation material, lunch and refreshments, for the registered delegate for the complete two days.
Group discount: Every 4 delegates the fifth is **FREE** , delegates must register at the **same time**.
Cancellation/Substitutions: You must notify us in writing (fax) by **May 8, 2015**. before the conference date to cancel to receive a refund. No cancellation will be accepted after that date. Notify us by Fax for any substitutions. ASAP.
Accommodation Information: Registered delegates will have a corporate rate available through proGamma science Corporation at the Holiday Inn, Pointe Claire Montreal. To reserve a room and take advantage of this special rate call **(514) 695-7110** for Montreal and ask for the proGamma ScienceCorp. discount.