Packaging for Pharmaceuticals - Innovation, Design, Testing
Temperature Controlled Packaging for Pharmaceutical Products, Biologics, Combination Products

Benefits of attending this comprehensive course will include:

- Perform sustainable drug stability studies
- Discuss FDA regulations surrounding thermal packaging
- Evaluate total cost of ownership for active and passive systems
- Cooperate with supply chain team when assessing suppliers
- Fine tune thermal profile testing solutions
- Implement data temperature loggers to better track the thermal profile
- Validate feasibility studies against industry standard profiles
- Focus on long term compliance initiatives during package design and testing

Design is not just what it looks like and feels like. **Design is how it works.**

Steve Jobs
Packaging for Pharmaceuticals-Innovation, Design, Testing
Temperature Controlled Packaging for Pharmaceutical Products, Biologics, Combination Products

Why should you attend?
Traditionally packaging design and logistical transportation have been in separate conversation but increased demands on pharmaceutical products have created a merger within the two groups. FDA regulations push for more package testing and validation of current systems and profiles. This course will focus on designing and testing thermal packaging solutions that consider the compliance and supply issues that most pharmaceutical manufacturers face on a daily basis.

Turning 'Theory' into 'Practice'
This interactive session will comprise lectures, interactive polling, roundtable discussions and workshops all aimed at understanding key strategies and identifying specific actions to effectively improve packaging success. The program will also include detailed, step-by-step guidance on how to develop, implement and maintain strategies in order to achieve a specific goal. Participants will want to come to the sessions with a thorough knowledge of improved company strategies and a willingness to discuss aspects of it in a confidential learning environment.

Key areas to be covered in the program and documentation

**Discussion of the Fundamental Element for Packaging Success**
- Start with a well-developed drug stability study
- Understand your drug temperature excursion performance
- Demonstrated drug stability best practices
- Cover a regulatory overview

**Thermal Packaging Design Fundamentals**
- Regulatory compliance and guidance-Industry regulations to consider and interpret
- Proper design of passive systems
  - Phase change materials
  - Insulators
- Add up the pros and cons of an active system
  - Additional cost
  - Level of protection required
  - Need for power supply
  - Availability for use
  - Flexibility of your supply chain
  - Extremities of external environment
- Consider the benefit of freight forwarders when entering international markets
- Summary of transportation and logistics industry
- Target suppliers that can benefit overall packaging success

**Test Thermal Packaging Systems**
- Develop and design your own thermal profile-compliance tool kit
- Discuss the pros and cons of industry standard profiles
- Implement industry standard profiles within your thermal packaging systems
- How to evaluate and validate thermal packaging systems
  - Complete proper feasibility and validation testing
  - Effective implementation of temperature data loggers
  - Protocol development tips and examples
- Test and confirm environmental chamber validation
- Learn chamber validation best practices from a firsthand account

**Industry Landscape—near term and longer term issues**
- Where is regulation headed?
- Developing your long term compliance program
- New tools, technologies and services for distributing temperature controlled, high value products

Who should attend?
marcus evans invites C-Level Executives including VPs, Directors, Senior-Level Managers and Strategic Leaders in the pharmaceutical industry with responsibilities in the following areas. We encourage the participation of more than one person from each company to facilitate the creation and implementation of your action plans:

- Packaging
- Packaging Engineer
- Packaging Development
- Packaging R&D
- Strategic Packaging
- Supply Chain
- Cold Chain
- Product Management

Duration of Course: 2 days
Dates: October 6-7, 2015 l Chicago, IL

The Institute of Packaging Professionals acknowledges this course as an approved packaging educational course. IoPP recognizes 1 CPE for each hour of attendance under the Certified Packaging Professional program. Both as a New CPP Applicant and / or a Recert Applicant.

Course Contact:
For more information on availability, course content and registration, please contact Emily Jones at emilyj@marcusevansch.com, 312 540 3000 ext. 6714.
Key to our success

marcus evans’ trainers are leading associate trainers. This ensures that our trainers are the best and most appropriate trainers for each individual course in terms of areas of expertise, training style, commercial industry experience and proven results. We choose trainers who are specialists in their respective fields and are dedicated to enhancing the skills and knowledge of our delegates through practical, interactive and applicable training.

About the Trainer: Karen Greene, CPP

Ms. Greene, CPP, is currently President, Life Pack Labs, a packaging testing laboratory and a MOCON/Life Packaging Technology business. Ms. Greene is also the Vice President, Life Packaging Technology LLC, a packaging engineering consulting and services firm. She has been a packaging engineering industry professional for over 30 years. Ms. Greene holds a Bachelor of Arts, Biology, degree from Holy Cross College in Worcester, MA and a professional certificate in engineering management from University of CA, San Diego. She is a certified packaging professional, CPP, the Co-President of the southern California Chapter of the Institute of Packaging Professionals and is a committee chairperson of the IoPP Medical Device Packaging Technical Committee and national board member of IoPP. Ms. Greene is a member of the ASTM F02, Flexible Barrier Packaging committee. She is an ISTA 7E (thermal design and validation) certified auditor.

Ms. Greene is a lead industry consultant for medical device and pharmaceutical package development, validation and production implementation projects and has solved problems related to sterile barrier package integrity, package design, test method development and test method validation and packaging quality related issues, utilizing testing expertise throughout. Her expertise extends to cold chain packaging issues, as well. She has held leadership positions with Edwards Lifesciences and IMED Corporation for teams responsible for packaging engineering, documentation, configuration management and label development functions within the medical device industry.

Ms. Greene is sought after for her expertise in developing action plans for compliance to international packaging regulatory standards as well as solving packaging performance problems. Ms. Greene has developed packaging testing expertise through her direct employment and consulting experience which includes decades of executing packaging validation plans and packaging development programs. She has authored several articles, presented at numerous conferences and conducted webinars on the topic of medical packaging, statistical rationale development for packaging validations and packaging testing issues.

Training style – Making Training Dynamic & Interactive!

Our trainers are selected on their ability to inspire, motivate and empower delegates. This is achieved by delivering training that is dynamic and relevant to the day-to-day challenges delegates face in the real world. All of the training courses offered represent a blend of tried and tested methods as well as the latest tools, techniques, market research, case studies and dynamic ways of thinking.

A maximum of 12 delegates per course in deluxe training venues allows for interactive training through group discussion, role-plays and exercises giving delegates the “how to” applicable and adaptable skills that they can use on returning to work.

Course content – Making It Relevant!

All delegates complete detailed pre-course questionnaires before the event enabling trainers to tailor course content in order to meet specific delegate needs. Delegate objectives are revisited before, during and after the event allowing us to focus on outcomes and address any delegate concerns as and when they arise. Where applicable, our trainers also act as coaches in providing one-to-one advice and feedback both during and after the course. To support your learning, we provide extensive documentation on all courses including, theory, models, exercises, worksheets, case studies, action plans, slides and further reading and reference material.

Course information

Upon receipt of your completed registration form you will receive formal confirmation of your booking. Approximately three weeks before the respective course you will receive all pre-course information including joining instructions, course timings, venue and accommodation information and pre-course questionnaires. Should you need to make travel and accommodation arrangements prior to receiving this information then please do not hesitate to contact a member of our team on 312 540 3000 EXT 6714.

Further information

Please visit www.marcusevanspt-us.com for further course information and training resources including:

- Course Booking and Administration Notes
- Accommodation Booking Service
- Special Offers and email Updates
- Recommended Reading Materials
- Training Articles and News
- Over 60 Public Course Outlines and In-Company Training Solutions

In-company training solutions

If you have a number of delegates with similar training needs then you may wish to consider having a cost-effective in-company training solution delivered locally or on-site. Courses can be tailored to specific requirements or developed as bespoke solutions. We also deliver activated teambuilding and leadership in-company workshops. Book now on 312 540 3000 EXT 6714.

marcus evans professional training courses combine the latest tools, techniques, market research, case studies and dynamic ways of thinking, delivered by experienced trainers to ensure the skills and knowledge acquired are directly applicable to your organisation.

Research the latest concepts, tools, techniques and tried and tested methods
Trainers the highest standard of dynamic trainers with cross-industry experience
Tailored detailed pre-course questionnaires to address your objectives
Applicability training relevant to your needs and your workplace
Interactive limited numbers with group exercises, role-plays and feedback
Action planning, implementation and follow-up
Documentation comprehensive supporting notes and further reading materials
Venue deluxe facilities supporting the training environment

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