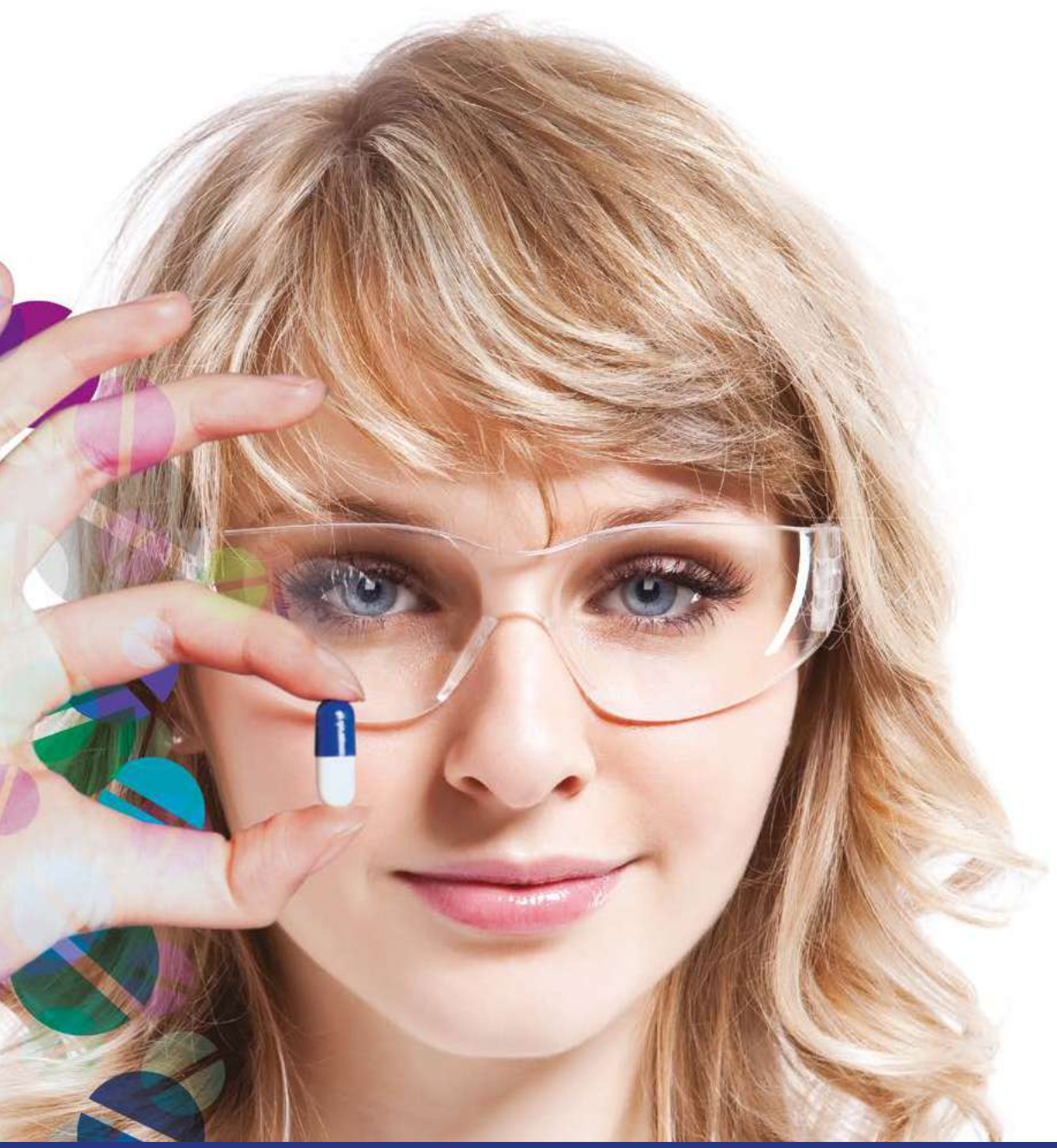


Making Pharmaceuticals

Research to Finished Product

NMM Exhibition Centre, Birmingham

28-29 April 2015

29th April 2015

11.50 - 12.10

The Latest Developments, Technologies and Strategies in Anti-counterfeit and Tamper-resistant Packaging

Andrew Love

Be4ward

Making Pharmaceuticals

www.makingpharma.com

Supported by:

BCMPA

EXCiPACT

Institution of Mechanical Engineers

CQI

University of Leeds

pharmig

Media Partners:

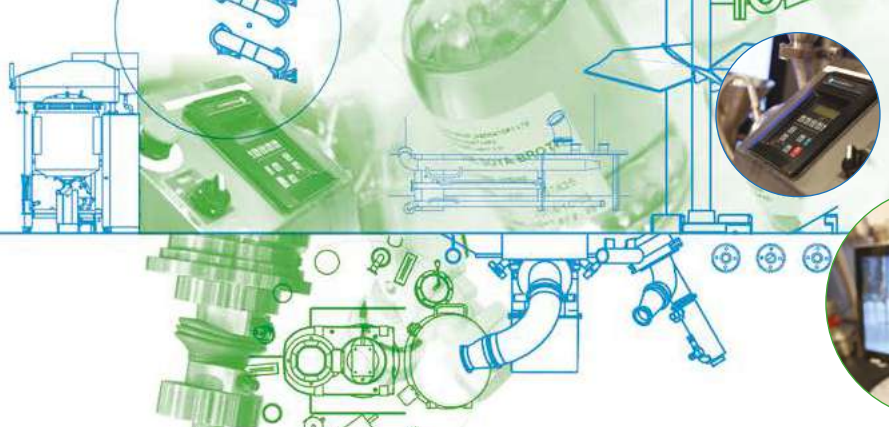
epm Connecting Pharma

manufacturing CHEMIST PHARMA

PHARMA

the Medicine Maker

Pharmaceutical-Tech.com



Making Pharmaceuticals is the only event in the UK dedicated to the detailed and complex issues associated with sourcing, manufacturing, outsourcing and delivering consistent pharmaceutical products to the market.

Source Manufacture Outsource

Research to Finished Product

Making Pharmaceuticals is designed to help industry improve manufacturing processes, address product formulation / reformulation, reduce undesired variability, deliver consistent product quality, improve process robustness and enhance efficiency.

It is also a focus for outsourcing in the pharmaceutical industry featuring a full range of contract services for licence holders, brand owners and manufacturers looking for outsourcing options from research and clinical trials, to manufacture, packing and delivery.

FIND OUT HOW TO:

DISCOVER
New APIs, Excipients and Other Innovative Technologies

ASSESS
The Latest Ingredients and their Potential Applications in your Business

MANAGE
Risk in the Supply Chain and Your Production Facility Using FMEA

ACHIEVE
Reliable, Efficient Manufacturing and Packaging Processes

EXPLORE
The Scientific, Technical and Processing Innovations Shaping the Industry

DEVELOP
Safe, Secure and User-Friendly Packaging for Pharmaceutical Products

COMPLY
With Increasingly Complex Global Regulatory Frameworks

EVALUATE
Potential Partners, Suppliers, Customers and Third-Party Service Providers

PROTECT
Your Business and Customers through Effective Monitoring and Compliance

ROOM A Tuesday 28 April

08.45 - 09.15 Event Opens

Technology Trends Facing the Pharmaceutical Industry

09.15 Data Integrity - The Compliance Questions for Both Buyer & Seller
David Thompson, Clarity Compliance

09.35 Recent Pharmacopeial Technology Changes for Elemental Impurities and Analysis
Thomas Paynter, Butterworth

09.55 Applications of X-ray Microtomography (XRT) in The Pharmaceutical Industry
Rene Friedrichs, RSSL

10.15 - 11.30 Break

Pre-Clinical

11.30 Optimising the Toxicology Opportunity
Chris Collins, QSCL

11.50 Drug Stability: Discovery, Development Through to Registration
Dr John Little, Cobra Biologics

12.10 The Successful Application of ASAP Software for Shelf Life Prediction of Pharmaceuticals
Gordon Wilson, Catalent Pharma Solutions

12.30 - 14.00 Break

Clinical

14.00 Designing Outsourced Clinical Trials Minimise the Impact of Principal Agent Theory Issues
Roger Joby, 1to1to1

14.20 Top Tips to Help You Sail Through Ethics Review
Jane Lamprill, Paediatric Research Consultancy™

14.40 Patient Recruitment Challenges
Jenny Christian, Venvera Limited

15.00 - 15.45 Break

Quality by Design

15.45 Quality by Design Approach to Product Development
Dr Michael Goodman, De Montfort University

16.15 Quality by Design Principles and Tools for Pharmaceutical Product Manufacture
Dr Walkiria Schlindwein, De Montfort University

Organised by: De Montfort University

ROOM A Wednesday 29 April

08.45 - 09.15 Event Opens

Regulatory

09.15 CMC Development – Intelligent Planning for Regulatory Success
Matt Burton, Jenson R+ Limited

09.35 Elemental Impurity Regulations - Where We Are Now And Where Do We Need To Be
Alan Cross, RSSL

09.55 Outsourcing Stability Studies to Contract Laboratories; Optimising Success
Kerry Bradford, Intertek

10.15 - 11.30 Break

Market Authorisation

11.30 Generic Registration
Peter Wittner, Interpharm Consultancy

11.50 NIR PAT Applications for Pharmaceutical Industry and Its Uses in Process Monitoring
Dr Gabi Levin

12.10 Gene Therapies

12.30 - 14.00 Break

Pharmaceutical or Not? Regulatory Choices for the Developer

14.00 Understanding Adjacencies Between Medicines, Cosmetics and Other Borderline Products
James Hall, JensonR+ Limited; Janet Worrell, consult2deliver

14.20 Reporting Practices Including Pharmacovigilance
Janet Worrell, consult2deliver; James Hall, JensonR+ Limited

Organised by: consult2deliver

14.40 - 15.00 Break

Lifecycle Management / Line Extension

15.00 Trends and Innovations in Life Cycle Management
Laura Harris, Bright Light Research

15.20 Right Form, Right Time: Using Solid State to Maximise Value Throughout the Drug Lifecycle
Dr Noel Hamill, ALMAC Group

For the latest programme and to register online, visit www.makingpharma.com

ROOM B Tuesday 28 April

08.45 - 09.15 Event Opens

09.15 Key Points for an Environmental Monitoring Programme
Dr Tim Sandle, BPL

09.35 Regulatory Requirements for Disinfectants
Rachel Blount, ECOLAB

09.55 Micro Data Trending and Review: Using Test Data Effectively

Organised by: Pharmig

10.15 - 11.30 Break

Scale-up

11.30 Scale-up: Pitfalls & Challenges
David Brown, BHR Group

12.00 Scale-up: Qualification & Validation
Karen Stevenson and Richard Briggs, GSK

Organised by: Institution of Mechanical Engineers

12.30 - 14.00 Break

Processing

14.00 Operational Excellence in Pharma Manufacturing and Packaging
Chris Hurst, GSK

14.20 Managing Lead Time to Achieve Stock Reduction
Richard Briggs, GSK

14.40 Achieving Process Reliability
Adrian Wallis, SPE Solutions

Organised by: Institution of Mechanical Engineers

15.00 - 15.45 Break

Risk Management

15.45 Risk Management/Failure Mode and Effects Analysis (FMEA)
Bob Hayes, SeerPharma (UK); Adrian Wallis, SPE Solutions

16.05 Change Control and CAPA
Bob Hayes, SeerPharma (UK)

16.25 Hosting a Successful Regulatory Inspection
Mukesh Patel, CommQP

Organised by: Institution of Mechanical Engineers

ROOM B Wednesday 29 April

08.45 - 09.15 Event Opens

New Technologies & Practical Applications

09.15 Process Development and Production of Custom Items at 1 - 200 Kilos
Dr Dave Compton, ProSynth

09.35 Microbiological Validation of the Use of Irradiation for Medicinal Products
Charlotte Byrne, Synergy Health

10.15 - 11.30 Break

Packaging Solutions

11.30 Novel Packaging Solutions for Improved Usability, Reduced Anxiety and Positive Responses
Stephen Wilkins, The Child-Safe Packaging Group

11.50 The Latest Developments, Technologies and Strategies in Anti-counterfeit and Tamper-resistant Packaging
Andrew Love, Be4ward

12.10 Selecting Materials for Container Closure Systems for Pharmaceuticals
Andrew Feilden, Smithers Rapra

Organised by: Be4ward

12.30 - 14.00 Break

Risk-Based Approach to Compliant GxP

14.00 GAMP® 5 – Managing Innovation and Compliance
Chris Clark, Ten Ten Ten Consulting

Organised by: ISPE UK

14.40 - 15.00 Break

Innovative Pharmaceutical Manufacturing

15.00 Process Analytical Technology (PAT)
Dylan Jones, Sanofi Avensis

Organised by: ISPE UK

For the latest programme and to register online, visit www.makingpharma.com

ROOM C Tuesday 28 April

08.45 - 09.15 Event Opens

Supply Chain Risk Management

09.15 Supply Chain Risk Management
Steve Moss and Phil Butson, PQG

09.35 Supply Chain Risk Management Workshop with Interactive Application Scenarios
Steve Moss and Phil Butson, PQG

Organised by: Pharmaceutical Quality Group (PQG)

10.15 - 11.30 Break

PS9000 Application Standard

11.30 PS 9000 Standard for the Manufacture of Packaging Materials for Medicinal Products
Dave Abraham, QRS-Associates Ltd

11.50 PS 9000 Workshop with Interactive Application Scenarios
Dave Abraham, QRS-Associates Ltd

Organised by: Pharmaceutical Quality Group (PQG)

12.30 - 14.00 Break

Excipients Certification

14.00 Independent 3rd Party Certification of Manufacturers, Suppliers and Distributors of Pharmaceutical Excipients
Dr Iain Moore, EXCiPACT

14.30 What to Look for in a Credible 3rd Party Auditing and Certification Programme of Suppliers of Pharmaceutical Excipients
Dr Iain Moore, EXCiPACT

Organised by: EXCiPACT

15.00 - 15.45 Break

The Future of Pharma in the UK

15.45 Biosimilars; Oh UK Where Art Thou?
Dr Duncan Emerton, The Biosimilarz Blog

Organised by: Biosimilarz

ROOM C Wednesday 29 April

08.45 - 09.15 Event Opens

Excipients: Quality, Safety and Functionality

09.15 IPEC Europe: Harmonised Standards for Pharmaceutical Excipients
Dr Iain Moore, Croda International plc

09.35 Quality by Design for Excipients – A Checklist for Suppliers and Users
Liz Meehan, Astra Zeneca

09.55 The IPEC Significant Change Guide 2014, When to Notify Excipient Users There Has Been a Change.
Dr Iain Moore, Croda International plc

Organised by: IPEC Europe

10.15 - 11.30 Break

Predictive Tools

11.30 Visual Habit: Predicting Crystal Properties
Dr Jonathan Pickering, University of Leeds

12.00 Developing Predictive Tools for Design and Manufacture of Particulate Products
Dr Ali Hassanpour, University of Leeds

Organised by: University of Leeds

12.30 - 14.00 Break

Ingredients

14.00 Hot Melt Coating for Pharmaceutical Applications
Dr Kathleen Allain, SEPPIC

14.20 Bittermask Coating: Improving the Palatability of Bitter API's
Tony McGorisk, SURFACHEM

14.40 - 15.00 Break

15.00 The Use of Acrylic Ion Exchange Resins as Taste Masking Systems for Bitter Drug Actives in Oral Dosage
Richard Summers, Azelis UK Life Sciences

15.20 Analytical Technology Transfer
John Wood, Almac

The Exhibition

The exhibition is an effective opportunity to see what is available on the market, discuss key issues and come away with clear approaches in mind. Please visit the web site to register, to qualify for benefits and for everything else you need to know.

Just some of this year's exhibitors...

A J Tyzack & Co.
Adelphi Healthcare Packaging
Adept Pure Water
Allied Pharma
ALMAC Group
APP Electronics
ARC Pharma
Ash Scientific
Azelis UK Life Sciences
Becton Dickinson UK
Binder
Bosch Packaging Technology
British Contract Manufacturers and Packers Association
Butterworth Laboratories
Caleva Process Solutions
Cantel Medical UK
Catalent Pharma Solutions
Clarity Compliance Solutions
Cole-Parmer
Custom Pharmaceuticals
Escubed
EXCiPACT
Exova
Fleet Laboratories
Fullbrook Systems
Griffon Management
High Force Research
Hologic
IMC Group
Institution of Mechanical Engineers
Intertek Health and Beauty Products Group
IPEC Europe
ISPE UK
Kerry Ingredients and Flavours
Lubrizol
Lucideon
Manufacturing Chemist
Pharmaterials
Pharmig
PPMA
Procept
ProSynth
Quality Control North West and Stockport Pharmaceuticals
Reading Scientific Services
Riva Europe
SEPPIC Air Liquide Healthcare Speciality Ingredients
Silverson Machines
Smithers Rapra
Solid Form Solutions
Steritech
Surfachem
Synergy Health
Tomorrow The World
TOXIKON Europe
Trinity Scientific
University of Leeds
Wickham Laboratories
Ytron-Quadro (UK)

For the latest exhibitor list and to register, visit www.makingpharma.com

For the latest programme and to register online, visit www.makingpharma.com

Making Pharmaceuticals is designed to bring together everyone involved in the development life cycle leading to commercial manufacturing of pharmaceuticals and provides an essential focus to the many different skills and range of expertise necessary to deliver consistent products.

During the 2-day period of Making Pharmaceuticals, visitors are able to attend a series of seminars compiled by a number of leading authorities in the UK.

Ideas Information Answers

Making Pharmaceuticals provides a forum that will help attendees to solve current challenges and to prepare for the ones to come.

The attendee profile includes:

- Chemists & Formulators
- Consultants
- Engineers / Engineering
- Importers
- Management
- Marketing & Business Development
- Microbiologists
- QA / QC
- Qualified Persons
- Production
- Process Development
- Regulatory
- Validation Disciplines

FREE
There is no fee to attend the seminars or workshops