3rd Merck Millipore Pharma Forum 2012

/ EXCiPACT™ Launch –
The new Excipients certification program

/ QP responsibility with regard to
GMP-compliant raw material

/ Liability issues when purchasing
deficient raw materials

/ Leachables and extractables testing

Tuesday, 12 June 2012
Darmstadt, Germany

Objectives

The Merck Millipore Pharma Forum has become an annual conference dealing with current developments in the field of pharmaceutical raw materials. The first two events attracted 100 delegates each.

Merck Millipore, a division of Merck KGaA and Concept Heidelberg has invited leading experts to speak at this year's event. Dr Iain Moore will present the brand new EXCiPACT™ Scheme which was launched in January 2012. EXCiPACT™ was initiated by a group of industry experts from the European Fine Chemical Group (EFCG), International Pharmaceutical Excipients Council (IPEC) Europe, IPEC Americas, European Association of Chemical Distributors (FECC), and the Pharmaceutical Quality Group (PQG) who have agreed to work together on the development of an international certification scheme for pharmaceutical excipients. It offers excipients manufacturers to certify their products and it offers pharmaceutical manufacturers to meet the new requirements to use GMP-compliant excipients.

Pharmaceutical raw materials are also the center of attention for the Qualified Persons. Two presentations provided by Merck and by European QP Association will highlight the challenges and possible solutions. In addition the legal situation of buyer and seller with regard to possible liability cases will be presented by a lawyer. Finally a subject of increasing importance for both industry and regulatory authorities will be highlighted: Leachable and extractable testing.

Target Audience

The Merck Millipore Pharma Forum is of interest for all colleagues involved in the manufacture and use of pharmaceutical raw materials. Representatives of industry (QA, QC, production, purchasing) and authorities are invited to join this event.

Get-together – Merck Millipore invites all speakers and participants!

On Monday 11 June - the day before the conference - at 18.00 h Merck Millipore invites all delegates to a "get-together" in the Welcome Hotel. Join us in a relaxed atmosphere for networking and discussions.

Guided Tour at Merck KGaA

The Merck Millipore Pharma Forum will be held in the "Atrium" on site at Merck KGaA in Darmstadt.

All participants are invited to join one of 3 tours as part of the Pharma Forum.

Option 1 Logistics process chain
Get to know Merck Millipore's high-bay warehouse and visit our distribution center.

Option 2 Investing in the future
Get to know our high innovative production plant for inorganic salts - the plant went on stream in 2011.

Option 3 History
Discover the company, brand and product history of the oldest pharmaceutical and chemical company in the world.

Please understand that representatives from competing companies may not join the tour option 1 and 2.
Participants will be informed in advance in that case.

Speakers

Dr Iain Moore, IPEC Europe and Croda Europe
Iain Moore is Coordinator of the EXCiPACT™ Certification Project at IPEC Europe. He is the co-author of a number of IPEC Documents for pharmaceutical excipients. At Croda Europe he is working as Product and Quality Assurance Manager.

Dr Bernd Renger, European QP Association
Bernd Renger has been working in pharmaceutical industry for many years. In his last position he was Director of Quality Control at Vetter Pharma Fertigung. Today he is Chairman of the European QP Association.

Frithjof Holtz, Merck Millipore, Darmstadt
Mr Frithjof Holtz is a biologist and has been working for more than 20 years with Merck KGaA, having a long year experience in quality assurance and regulatory affairs. As Director Advocacy he is responsible for the advocacy activities of the pharmaceutical raw materials business of the Merck KGaA Division, Merck Millipore.

Dr Martin Wesch, Wesch & Buchenroth Lawyers
Martin Wesch is a Lawyer and certified specialist in labor law and medical law.

Dr Christian Wolf, Central Analytical Services, Merck KGaA, Darmstadt
Christian Wolf is head of the laboratory for chromatography at Merck's central analytical service. He is responsible for Extractable & Leachable studies of different packaging materials of Merck.

Program
3rd Merck Millipore Pharma Forum, 12 June 2012

08.30 – 09.00 h	Registration
	Host: Dr Matthias Bucerius, Head Global Marketing Pharm Chemicals Solutions
09.00 – 09.15 h	**Opening** ***Dr Kai Beckmann, Member of the Executive Board of Merck KGaA and Mr Burghard Freiberg, Senior Vice President Pharm Chemicals Solutions, Merck Millipore***
09.15– 10.00 h	**The new EXCiPACT™ Scheme – GMP Compliance for Excipients** • New requirements from the Counterfeit Directive • What are the appropriate GMP standards for excipients • How to access the suitability of excipients • The certification procedure ***Dr Iain Moore, IPEC Europe***
10.00 – 10.45 h	**Performing of Extractables & Leachables Studies at Merck KGaA** • Case study of a real example • Data evaluation and risk assessment • Extractable study to obtain an overview about possible leachables • Evaluation by toxicology • Leachable study including quantitative data ***Dr Christian Wolf, Central Analytical Services, Merck KGaA, Darmstadt***
10.45 – 11.15 h	Coffee break
11.15 – 12.45 h	**Guided Tour at Merck KGaA**
12.45 – 13.30 h	Lunch
13.30 – 14.15 h	**New Responsibilities of the Qualified Person?** • Counterfeit Directive 2011/62 • QP Declaration Template and Supply Chain oversight • The role of the manufacturer's Quality Management System • How to obtain relevant information – cooperation with suppliers • How to obtain relevant information – cooperation with third parties • Contracts and agreements ***Dr Bernd Renger, Chairman European QP Association***
14.15 – 15.00 h	**Suitability of pharmaceutical Raw Materials dedicated to intended Use** • Regulatory requirements for pharmaceutical raw materials based on intended use • European Falsified Medicine Directive and related GMP requirement e.g. for excipients • Risk assessment of excipients based on the intended use • Positioning of pharmaceutical manufacturer and raw material supplier in order to address these challenging aspects ***Frithjof Holtz, Merck Millipore, Darmstadt***
15.00 – 15.30 h	Coffee break
15.30 – 16.30 h	**Liability Issues when purchasing deficient Raw Materials** • Responsibility of the buyer the seller • Product liability • Who is liable when nothing is defined in the contract • Liability compensation for consequential loss (final product can not be released for the market) • How to avoid problems - possible wording for contracts ***Dr Martin Wesch, Lawyer, Certified Specialist in Labor Law and Medical Law***
16.30 – 17.00 h	Panel Discussion
17.00 h	Bus transfer to the Hotel

Organizational Details

Date
Tuesday, 12 June 2012, 09.00 – 17.00 h
(Registration and welcome coffee 08.30 – 09:00 h)

Venue
The conference will take place in the "Atrium" at Merck KGaA in Darmstadt. Darmstadt is easily accessible via Frankfurt international airport. The taxi transfer takes approx. 25 minutes

Recommended Hotel
Participants may use the room contingent available at the
Welcome Hotel
Karolinenplatz 4
64289 Darmstadt, Germany
Phone +49(0)6151-3914 0
Fax +49(0)6151-3914 444
You will receive a room reservation form when you have registered for the event.

At 7.45 h, a bus shuttle from the Welcome Hotel to the Atrium at Merck Darmstadt will be offered to all participants.

Registration fee
€ 350,- plus VAT, includes lunch, all refreshments during the conference and the get-together.
The fee is payable after receipt of the invoice

Registration
By post, fax, eMail or online at
http://www.merck4pharma.com/forum

Conference documentation
All conference presentations will be available on a USB stick.

Any Questions?
For all questions regarding the organisation, hotel booking, registration, please contact
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For all questions regarding the content please contact Mr Oliver Schmidt,
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Organization of the Merck Millipore Pharma Forum
The Merck Millipore Pharma Forum is organized by Concept Heidelberg, Europe´s largest Conference Organiser in the field of pharmaceutical Quality Assurance

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Registration Form – Please fill in and fax to +49(0)6221 - 84 44 34

Transportation to the Merck Millipore Pharma Forum
○ I will make use of the Shuttle Service
○ I will arrive by car/taxi

○ Yes, I will join the get-together on Monday 11 June at 18:00h

I would like to join the following guided tour:
○ Logistics process chain
○ Investing in the future
○ History

Title, First Name, Last Name _____

Company _____ Department _____

Address _____

eMail _____ Phone / Fax _____

Place, Date _____ Signature _____

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!