Science based design of formulations and manufacturing processes for oral solid dosage forms – from preformulation to capable commercial processes

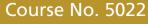
APV Expert Meeting: Manufacturing Classification System (MCS)

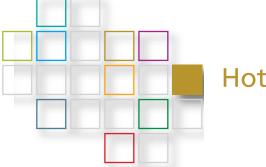


28 November 2017 Darmstadt, Germany

taking place at Merck KGaA in Darmstadt







Hot Topics

If you come to this workshop you will benefit from...

- Presentations from Big Pharma and CDMOs sharing their approach on how they select their manufacturing processes for phase III and commercial oral solid drug products
- Overview on chosen routes of manufacturing for commercial and late stage investigational products from several companies, including some data which has never been published before
- The opportunity to contribute to a peer-reviewed publication with authorship credit and a contribution to a novel approach of scientifically driven decision making
- The discussion with colleagues from international companies across the field of solid dosage forms in a unique working group atmosphere setting





Objectives

Objective

An international cross-industry and academia working group has proposed the development of a Manufacturing Classification System (MCS) for oral solid dosage forms based on processing route.

The question of which route of manufacturing to select for the commercial manufacturing of a new solid drug product is an important one for both new chemical entities and new generics and should be based on scientific data and the specific properties of both the compound and the dosage form. In order to help the formulator and process scientist to come up with a scientific rationale for their decision which could be applied throughout the industry a first preliminary concept has been published in 2015 "A proposal for a drug product Manufacturing Classification System (MCS) for oral solid dosage forms" (M. Leane, K. Pitt, G. Reynolds; Pharm Dev Technol, 2015; 20(1); 12-21).

However, this approach needs to be extended and progressed into a suitable working tool which can be applied widely throughout the community based on commonly available data.

Therefore, the MCS working group has teamed up with the APV's focus group on solid dosage forms to organize this joint expert workshop, inviting all scientist and experts across all areas of the pharmaceutical industry (from drug substance to drug product, from engineering to clinic), and experts from the regulatory authorities, as well as from academia to participate in this workshop for a more scientific and risk based decision making approach.

Program

Tuesday, 28 November 2017

09:00 to 18:00

Welcome address Michael Leane, BMS, UK Iris Ziegler, CordenPharma International, Germany

Introduction to MCS concept and summary of first paper Michael Leane, BMS, UK

Presentation of results obtained from regulatory filings and data gathering from industry so far

This includes data which has never been published before MCS core team

Can other companies provide similar data and which data are most important to use?

Contribute to this session and provide your input to case studies on model compounds and a pier reviewed paper Discussion on morning topics

Lunch

How are manufacturing processes selected by Big Pharma and CDMOs today?

"10 minutes presentations " from

Corden Pharma International - Iris Ziegler, Germany Janssen - Giustino Di Pretoro, Belgium Bayer - Susanne Skrabs, Germany Merck - Gero Hooff, Germany Boehringer Ingelheim - Georg Böck, Germany F. Hoffmann-La Roche - Aniko Szepes, Switzerland Astra Zeneca - Gavin Reynolds, UK BMS - Michael Leane, UK Pfizer - Neil Dawson, UK GSK - Kendal Pitt, UK

Coffee Break

MCS in continuous processing and other novel formulation techniques? Kendal Pitt, GSK

How can results from materials science characterization of APIs improve outcomes for formulators and assist MCS?

Neil Dawson, Pfizer

Have we enough data gathered to construct an improved MCS?

Wrap up discussion

Topics discussed during this Hot Topics Expert Meeting

- What do different functional areas define as "good API properties" for them?
- MCS and QbD: Can a science based product and process understanding combined with a risk based approach for the selection of manufacturing processes improve the efficiency of manufacturing of efficacious and safe drug products?
- What are API properties a MCS should address to help improve manufacturability?
- How can Materials Science characterization results of APIs improve outcomes for formulators?
- Can we define additional boundaries within the MCS?
- Excipients, intermediates and composite materials how can they help?
- MCS and Continuous Manufacturing can, should or must the MCS be applied to continuous manufacturing processes?
- Which routes have companies used in the past and why?
- What are the perceived defficiency and what is needed for a change for the future?

Participants are invited to send their specific interests and questions, together with their own personal background together with the topics they would like to see discussed during the workshop to the APV or to Iris.Ziegler@ cordenpharma.com when registering for the workshop.

Data for model compounds will be send out to all participant prior to the workshop for review and discussion during the workshop



Location

Merck KGaA Frankfurter Straße 250 64293 Darmstadt Germany

Date

Course no. 5022 from 28 Nov. 2017 to 28 Nov. 2017

09:00 18:00

Registration fee

Industry 50 EUR Authorities/Academia 50 EUR Students* 25 EUR (free of VAT according to § 4,22 UStG) Coffee breaks, lunch, dinner and

electronic proceedings included. *Limited places for full time stu-

dents available; written evidence

must be submitted.

Registration

APV-Geschäftsstelle Kurfürstenstraße 59 55118 Mainz/Germany Phone: +49 6131 9769-0 Fax: +49 6131 9769-69 e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current program information. My acceptance can be cancelled at any time in writing.

Mainz, May 2017

| Registration As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise. | Title, First Name, Last Name * | |
|---|---|---------------------|
| Registration confirmation After your registration was successfully processed, you will receive a confirmation. | Company Name* | |
| | Street/No. or P.O. box* | |
| Before the event A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc. | | |
| | Location* | |
| After the event You will receive a certificate confirming your parti- cipation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time. | Zip-Code* | |
| | Phone* | |
| Follow-up After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have. | Department* | |
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