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

Course No. 5022

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

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Hot Topics

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

APV Expert Meeting Manufacturing Classification System (MCS)

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

Registration by fax +49 6131 9769-69

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Location

Merck KGaA
Frankfurter Straße 250
64293 Darmstadt
Germany

Date

Course no. 5022
from 28 Nov. 2017 09:00
to 28 Nov. 2017 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 students available; written evidence must be submitted.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
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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.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

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.

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