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One-Day Virtual Seminar

The Use of Drug Master Files & Quality Agreements: Understanding and Meeting your Regulatory and Processing Responsibilities

By: **Robert J. Russell,** President and CEO, RJR Consulting, Inc.

Dates: June 22, 2020 (10:00 AM - 4:00 PM PDT)

Location: Virtual Training Through WebEx

Various parts of the country are still battling the Coronavirus (COVID-19), we will conduct the class 100% online.



SPEAKER

Robert J. Russell, President and CEO, RJR Consulting, Inc

Bob is a Global Regulatory and CMC expert with 28 years of prior industry experience in international regulatory management and compliance, global business development and global supply chain management. Mr. Russell formerly held senior leadership positions, in these functional areas, at Dow Pharmaceuticals and Cordis-Dow Medical Devices.

His experience and knowledge span Healthcare Authority's requirements and regulatory processes across Life Science products.

For the past 18 years, Bob has been President & CEO of RJR Consulting, Inc. The company assists the pharmaceutical, medical device and biotech industries in understanding Regulations affecting compliance and in conducting product registrations with their clients in more than 95 countries.
He holds a BS / MS in Chemistry.

COURSE DESCRIPTION

This combined DMF (Drug Master Files) and Quality Agreement training will discuss the advantages for suppliers and drug product manufacturers in developing these arrangements together.

Over time, there have been several misunderstandings between supplier / contractors and pharmaceutical / biologic finished product manufacturers. The root of many of the problems lie in a lack of a suitable agreement delineating roles, responsibilities and resolution to agreement to these issues. Part of these arrangements typically involve the development, support and updating of confidential technical files (Drug Master files), which allow suppliers to protect their confidential product and process information from each and every customer and share it only with the Agency.

The course will include the current review and enforcement climate within FDA and the manner, in which Drug Master Files (DMFs) are reviewed by FDA personnel. Besides the US, the use of DMFs in the EU, Japan, Canada and Australia will also be discussed. Similarities and differences to the U.S. system will be highlighted.

The conversion of paper to e-filings requirements with FDA will also be discussed. The process used for e-filings will be reviewed in detail. Maintaining filings for Annual Reports and DMF Amendments will also be covered.

Upon completion of this course, attendees will understand how to prepare Quality Agreements, Drug Master Files (DMFs) with the FDA and the rationale behind doing so. Participants will gain practical knowledge about what reviewers look for in DMFs, the consequences that can be expected as a result of non-compliance and the strategies for avoiding the most common DMF-related errors. The course will also emphasize the "organic" nature of DMFs, present strategies for establishing and maintaining effective change control programs, along with facilitating effective communications with regulatory agencies along with customers and vendors.

The course will also discuss the movement by U.S. FDA to convert from a paper filing system to electronic submissions for initial DMF submissions, annual updates and DMF amendments.

LEARNING OBJECTIVES

The course offers methodologies and techniques on:

Quality Agreements

- The Origin and Background around Quality Agreements
- When are Quality agreements appropriate?
- The Scope of Quality Agreements
- Quality Agreement Formatting and Content
- How to negotiate a Quality agreement

DMFs

- Who really needs a DMF and why?
- The various types of DMFs - which is best for your products.
- The relationship between DMFs and drug and biologics applications.
- The symbiotic relationship between DMFs and current Good Manufacturing Practices (c-GMPs).
- Common DMF errors - how to avoid them.
- How to deal with deficiency letters and their origins.
- Effective change control strategies.

AGENDA

DAY ONE (10:00 AM – 4:00 PM)

Quality Agreements

- The Origin and Background around Quality Agreements
- When are Quality agreements appropriate?
- The Scope of Quality Agreements
- Quality Agreement Formatting and Content
- How to negotiate a Quality agreement

What are DMFs?

- Types of DMFs (Types II, III, IV and V)

The rationale and preparation process for DMFs

- Why DMFs are important to you and your company
- How DMFs fit into FDA's regulatory processes for review of drug and biologic applications
- Why, more than ever, you may need DMFs to maintain current supplier agreements as well as to develop new business relationships
- What not to include

DMF Preparation: What you need and why you need it

- The essential components of all DMFs, including:
- The relationship between DMFs and c-GMPs
- Tactics for avoiding the most common DMF-related errors
- Tactics for dealing with unique or novel situations/unfavorable reviews

FDA Review: How FDA reviews DMFs and why.

- What you should expect throughout the DMF preparation and filing process
- How to communicate and work with FDA to ensure success

Components Associated with a DMF:

- DMF vs. Application
- Acknowledgement Letter
- Letter of Authorization
- Changes to a DMF
- Annual updates
- Obligations of a DMF holder
- Transmissions - transmittal letter
- Deficiency letter
- Auditing Vendor
- Inside tips
- Changes to DMF system in last 10 years
- Binder specifications and cover sample

Japan DMFs

European DMFs

Canadian DMFs

Change control and maintenance: Why accurately maintaining your DMFs is important

- DMFs as "living" documents. DMF updates and amendments
- Types of DMF-related changes that impact drug/biologic applications: production facilities, composite materials, manufacturing processes
- What you must report and to whom - the importance of establishing communication pathways with regulatory agencies, customers and vendors

WHO WILL BENEFIT

- Manufacturing
- Regulatory Affairs
- Project Managers
- Global Supply Chain
- Research and Development
- Quality Assurance & Control
- Validation
- Development and Preparation of Submission Materials
- General Management

Registration Form

Registration Information:

- **Register Online**. Click Here Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-201 871 0474.
- Call 201 871 0474 or Fax your PO: 253 663 7224 Pay your check to "PMA Conference Management" and Mail the check to: PMA PO Box 2303, Falls Church VA 22042. Please fill this form with attendee details and payment details and fax it to 253 663 7224

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ 201 871 0474 or email us @ register@pmaconference.com

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Seminar Topic: The Use of Drug Master Files & Quality Agreements: Understanding and Meeting your

Date & Location: Regulatory and Processing Responsibilities | June 22, 2020 (10:00 AM - 4:00 PM PDT)

Attendee Details Registration Fee: $799 per attendee.:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

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