2-day In-person Seminar:

Preparation of FDA Submissions and Communicating with the FDA (INDs, NDAs, BLAs, ANDAs, PMAs, 510(k)s, IDEs, Post-Approval Supplements)

Zurich Switzerland
June 20th & 21st, 2018
9:00 AM to 5:00 PM

David R. Dills
Global Regulatory Affairs & Compliance

David R. Dills, Global Regulatory Affairs & Compliance Consultant, Interim President, currently provides global regulatory affairs, compliance and quality consultative services for early-stage and established Class I/II/III medical device, including combination products, In Vitro Diagnostics, nutraceuticals/supplements, cosmetics and biopharmaceutical manufacturers in multiple medical specialties and therapeutic areas on the global landscape, and has an accomplished record with more than 26 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities by medical device manufacturers and consultancies, including a globally recognized CRO and has worked directly with manufacturers engaged in compliance remediation activities and services involving consent decrees, CIA’s, warning letters, 483 observations, and customer generated compliance events, and prepares for and conducts QS and regulatory audits.

Why you should attend:
• What do the regulations say?
• Navigate the FDA drug and device approval system
• Prepare, construct and submit well-written IND, NDA, BLA, PMA, 510(k) and IDE submissions and regulatory filings
• Navigate the FDA review process
• Identify the required regulations and guidance documents for drug and biologic submissions
• Use regulations and guidance documents to outline and construct a variety of drug and biologic submissions

Price

Price: $1,895.00
(Seminar for One Delegate)

Register for 5 attendees
Price: $5,685.00 You Save: $3,790.0 (40%)*
$9,475.00

Register for 10 attendees
Price: $10,422.00 You Save: $8,528.0 (45%)*
$18,950.00

**Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.

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## Agenda:

### Day One

**Lecture 1: Medical Devices**
- The recent changes in the 510(k) program and guidance documents relating to both 510(k)s and PMAs
- How to identify and assess the regulatory requirements
- How to meet the regulatory requirements in a systematic, integrative manner
- How to increase a 510(k) and PMA submission quality
- How to format succinct and comprehensive 510(k) and PMA submissions
- When to submit a 510(k) for a new or modified product
- Types of 510(k) submissions and when to use each
- What is the submission process?
- What is contained in a 510(k) submission package?
- How to know whether clinical data is required.
- How is the submission package assembled?
- User fees and 510(k) submissions
- How to interact with the FDA and the reviewer
- What to do if you make a change to your device
- What is "regulatory logic" and how can we use it to our advantage?
- What is and is not a regulated medical device?
- How do we "design" or labeling (i.e., stated claims vs. inferred/implied claims)?
- How can we "advertise" off-label use?
- What is competitive regulatory strategy (i.e., how can I use regulation as a barrier to entry to my competition)?
- What is the medical device classification system?
- Why do we have a classification system? Why is it important?
- How do I determine classification?
- Can I change classification?
- How can I use classification to my advantage?
- How does classification vary in other parts of the world?
- What are the major pathways to market?
- Premarket Notification a.k.a. 510k
- Premarket Approval (PMA)
- de Novo regulatory pathway and when to use it
  - Which do I choose and when?
  - Must I use only one? Can I mix and match?
  - What is the Pre-Market Notification (PMN) a.k.a., 510k?
  - How can I use the 510k to my advantage?
- What does substantial equivalence really mean?
- Why are many 510(k)’s rejected and how do I avoid being in the majority?

### Day One

- What types of 510(k’s exist and how do I choose?
- What are the two most important components of a successful 510k?
- When and how can I use the split- and multiple predicate strategies safely and effectively?
- What is predicate creep?
- If I change my device, must I tell FDA (special 510k vs. letter-to-file)?
- What is the future of the 510k?
- Steps to develop a PMA submission strategy
- Best practices of quality system information for PMA applications
- What to expect during a submission review
- Preparation needed for an advisory panel meeting
- Tips to prepare for an inspection
- Ins and outs of BIMO inspections
- How to deal with unexpected clinical outcomes, animal test results, and adverse panel recommendations

### Day One

- Needed supplemental submissions for approved PMAs
- Where does the PMA fit in the medical device universe?
- Why PMA’s are rejected and how do I avoid being one of them?
- How does the 510(k) compare to the PMA?
- When is an IDE ‘required’ and when is it not (i.e., SR vs. NSR)?
- What types of PMA’s exist and how do I choose?
- What goes into a successful PMA?
- When do I need a clinical trial and how do I design one?
- Key steps for the De Novo Pathway
- What is the de novo and how does it compare to the 510k?
- Why is the de novo the fastest growing pathway to market in the US?
- How can I use the de novo to my competitive advantage?
- Communication with FDA: The Pre-Submission Process
- When and how should I communicate with FDA?
- What is a pre-sub and should we use it?
- What is a successful pre-sub and why are most not successful?
- How early should we talk to FDA?
- What do we need to include/should we include in the pre-sub?
- Should we meet in person? How do we prepare?
- What happens after the pre-sub? Are the results binding?
- What are the regulatory challenges of combination products, tissue engineering and biomedical nanotechnology?

### Bonus Topics

The following topics are discussed throughout the course:

- How do I integrate regulatory strategy and reimbursement strategy?
- What goes into an international regulatory strategy
- What is regulatory risk and how do I factor it into my regulatory strategy?
- How can I use guidance documents to my competitive advantage?
- What is usability and where does it fit into regulatory submissions?
- What’s the difference between writing a regulatory submission vs. designing a regulatory submission?
- Learn the appropriate and expected regulatory strategies and guidelines for your drug and device submissions
- Pre-submissions are made to the FDA in order to request FDA feedback
- Pre-subs are used for various reasons including meeting requests, to study risk determination, for submission issues, and for FDA feedback to specific questions related to a pending submission or protocol
- The de novo pathway for device marketing rights was added to address novel devices of low to moderate risk that do not have a valid predicate device
- Upon successful review of a de novo submission, FDA creates a classification for the device, a regulation if necessary, and identifies any special controls required for future premarket submissions of substantially equivalent devices
- What can I find additional information?
- Definitions and Marketing Overview
- Pre-Submission Meetings
- Clinical Investigations of a Medical Device
- IDE Exemption
- Understand the application process and administrative action with your IDE
- Know the responsibilities of the sponsor
- IRB review and approval and expectations
- What records and reports are expected and required
- IDE refers to the regulations under 21 CFR 812
- Know the procedures involved with the clinical studies and expectations
- Understand that if the study involves a significant risk device, the IDE must also be approved by FDA
- SR/NSR Determination and the IDE

Where can I find additional information?
Agenda:

Day Two

Lecture 1: Drugs/Biologics
- Review and approval procedures for drug and biologics submissions/regulatory filings
- Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA. There are three IND types.
- FDA Division Information: Submission Basics; Outlining the submission, creating the Table of Contents, timing of submission/timelines, contributions from other departments, editing, style guides, templates, supportive documents, QAing the submission
- Publishing the Submission: Submission publishing basics; Copies (how many to make and keep); Introduction to electronic publishing requirements
- Tracking the Submissions: Creating the index history; Creating an issues log
- Common Technical Document Format Regular Copy
- Pre-Market: FDA Meetings (Type A, B and C); Pre-IND, Phase I, Phase II, End of Phase II, requesting the meeting, preparing the meeting package, meeting minutes; The IND Submission; Routine IND Submissions: Clinical, Non-Clinical, CMC, Annual Reports. Investigator Brochure updates, protocol/protocol amendments, Investigators; Additional IND submissions: Fast track, orphan drug, special protocol assessment
- Marketing Application: NDA in a CTD Format
- NDA Forms and Electronic Submissions
- Guidance Documents for NDA's and ANDA's
- NDAs and BLAs: Filing Refusal to Accept Application for Filing From Applicants

Lecture 2: Abbreviated New Drug Application (ANDA)
An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route and intended use.

The Generic Drug Approval Process
- What is the Approval Process for Generic Drugs?

Lecture 3: Biologics License Application (BLA)
The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680. A BLA is submitted by any legal person or entity who is engaged in manufacture or an applicant for a license who takes responsibility for compliance with product and establishment standards. Form 356h specifies the requirements for a BLA. This includes:
- Applicant information
- Product/Manufacturing information
- Pre-clinical studies
- Clinical studies
- Labeling

Lecture 4: Investigational New Drug (IND) Application
IND Process: FDA IND Form 1571; cover letter; table of contents; introduction; investigational plan; chemistry, manufacturing, and control; nonclinical studies (pharmacology and toxicology); clinical studies; investigator brochure; labeling; USAN procedures; compiling IND; IND filing; IND review process; amendments to IND; safety reports; annual reports; IND withdrawal; IND termination

Lecture 5: New Drug Application (NDA)
NDA Process: FDA NDA Form 356(h); cover letter; index; labeling; summary; chemistry section (chemistry, manufacturing, and controls information; samples; methods validation package); nonclinical pharmacology and toxicology section; human pharmacokinetics and bioavailability section; clinical data section; safety update report; statistical section; case report tabulations; case report forms; patent information on any patent which claims the drug; patient certification; establishment description; debarment certification; field copy certification; user fee cover sheet; compiling NDA; NDA amendments; NDA review process; post-approval requirements

The resources for application reporting and applications procedures apply to IND applications for both clinical research and clinical treatment

- Pre-Investigational New Drug Application (Pre-IND) Consultation Program
- Legal Basis for FDA's Authority to Regulate Chemical Drugs, Biologics and Biopharmaceuticals

Overview of human medicine regulation by the FDA
- Drug regulatory pathways granted to the FDA by U.S. Congressional laws
- Human medicine distinctions: chemical drugs vs. biologics, CDER vs. CBER, generics vs. biosimilars
- FDA Regulatory Drug Development Review and Approval Process

FDA's requirements/expectations for CMC, Nonclinical, Clinical content from Phase 1 through market approval

- Differences in the FDA regulatory review and approval pathways for NDAs, BLAs, ANDAs and biosimilars
- Accelerated and fast track FDA review opportunities
- Meeting with the FDA
- PDUFA, GDUFA and other meetings with the FDA - justified not entitled
- Risk assessment - when should you have a meeting with the FDA

- Lessons learned of what to do/not to do
- Critical Importance of FDA Submissions and Communication during the IND Stage
- What the FDA is looking for in IND submissions/amendments - avoiding the 'clinical hold'
- Forms, format and content required during the clinical stages
- Strategic value of the critical meeting with the FDA
- Critical Importance of the FDA NDA/BLA/ANDA
- Dossier Preparation
- Need to avoid the Refusal to File
- What the FDA is looking for in the market application dossier - forms, format, content
- Strategic value of the Pre-NDA/BLA submission meeting with the FDA
- FDA Review and Approval of the NDA/BLA/ANDA Submission

Day Two

- First milestone - avoiding the ‘Refusal to File’
- Intense interactions with the FDA covering CMC, Nonclinical and Clinical
- Race to meet the time clock - avoiding the Complete Response Letter
- Post-market Approval Submissions and Interactions with the FDA
- Supplements for changes in CMC and Clinical, and required FDA reporting/updating
- Honoring post-market approval commitments and ongoing adverse event reporting
- Navigating the Rich FDA Website Resources
- On-line resources for Drugs
- On-line resources for Biologics
- Insights into the FDA NDA/BLA review process

Lecture 6: Case Study Practice
Practice on a project relevant to participants' organization

Lecture 7: Interactive Exercises and Discussions
Drug and Medical Device Submissions and FDA Communications and Meetings

Recap of Day 2

Questions and Summary
2-day In-person Seminar:
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Group Participation

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What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry’s top notch professionals

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Contact Information: Event Coordinator
NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com
www.globalcompliancepanel.com

Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar GlobalCompliancePanel