2017 SPEAKERS

John W. Smith, Director, Regulatory Affairs, **Allergan**
Anthony Bantug, Principal Engineer, **Amgen**
Kenneth Tan, Senior Packaging Engineer, **Amgen**
Catherine Segura, Senior Manager, Systems Engineering Operations, **BD Biosciences**
Robert S. Bottome, Executive Director, Global Supply Chain, **BioMarin**
Carla Vidal, Manager of Drug and Device Manufacturing, **Dermira**
Michele Goodwin, RA/QA Manager, **Entra Health**
Alfred Shihata, President and CEO, **FemCap**
Lisa M. Kelsey, Head, Commercial Labeling, **Genentech**
Gail Tennyson Hicks, Associate Program Director, **Genentech**
Steve Kemmerrer, Vice President Engineering Development, **Inovio Pharmaceutical**
Priya Hays, Technical Writer, **Kite Pharma**
Rich Horn, Director, Clinical Supplies, **Nektar Therapeutics**
Santiago Beltran, Principal Packaging Engineer, **NuVasive**
Xiaojing Liu, Assistant Professor, **San Jose State University Packaging Faculty**
Keith Schlotthauer, Packaging and Labeling Design, **Stryker Neurovascular**
David Larwood, CEO, President, **Valley Fever Solutions**

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PACKAGING THAT SELLS YOUR PRODUCT

	Pharma and Device Packaging and Labeling West Coast **November 28th** **Program Day One**
08:00	Registration and refreshments
08:45	Chair's opening remarks ***Gail Tennyson Hicks,*** *Associate Program Director,* ***Genentech***
09:00	**Panel: Establishing perfect communication within different departments to improve every step in the development process** • Encouraging regular cross function meetings across design process to ensure compatible packaging • Establishing pragmatic communication from the beginning for selection of materials and sterilization methods • Working directly with labeling group to review artwork and ensuring technical requirements are met • Building relationships and good teamwork through defined team structures to create structured action plans • Ensuring a successful launch through open communication and precise questioning to colleagues in different sites ***Catherine Segura,*** *Senior Manager, Systems Engineering Operations,* ***BD Biosciences*** ***Robert S. Bottome,*** *Executive Director, Global Supply Chain,* ***BioMarin*** ***Alfred Shihata,*** *President and CEO,* ***FemCap*** ***Steve Kemmerrer,*** *Vice President Engineering Development,* ***Inovio Pharmaceutical***
09:30	**Session reserved for Blue Software** ***Content TBC***
10:00	**Achieving greater cooperation between cross-functional teams to streamline your product launch and change control systems** • Achieving greater collaboration between package design/engineering, labeling, artwork, marketing, regulatory, manufacturing, and supply chain departments to meet deadlines for product launches and updates • Establishing clear lines of communication between cross-functional departments to streamline product approval protocol • Implementing an effective approvals tracking system to easily identify outstanding tasks that delay product launches and updates • Eliminating the guesswork involved in updating packaging, labeling and artwork within manufactured drugs • Maintaining and updating systems which promote built-in flexibility and consider changing global regulation ***Lisa M. Kelsey,*** *Head, Commercial Labeling,* ***Genentech***
10:30	Morning refreshments and networking
11:00	**Panel: Evaluating modifications to your packaging process to better adapt to your current study** • Appreciating different processes solutions to adjust your approach on products' unique characteristic

	• Working proactively with manufacturing organizations through meetings for developing common strategies • Organizing right number of audits to comply with FDA quality requirements and launch your products • Examining necessity to modify manufacturing process to ensure a rapid problem solving in case something unexpected happened • Changing swiftly a packaging component to shift to a new component needed ***Carla Vidal,*** *Manager of Drug and Device Manufacturing,* ***Dermira*** ***Anthony Bantug,*** *Principal Engineer,* ***Amgen***
11:30	**Session reserved for Perigord** ***Content TBC***
12:00	**Assessing cryogenic secondary packaging operations** • Analyzing challenges to ensure an optimal packaging a cryogenic product • Addressing solutions for a great packaging assembly in cryogenic temperatures • Exploring new possible labeling and packaging solutions in this field to overcome potential issues ***Kenneth Tan,*** *Senior Packaging Engineer,* ***Amgen***
12:30	**Session reserved for Global Vision** ***Content TBC***
13:00	Lunch and networking
13:30	**Appreciating challenges brought by multiple layers packages to thrive in new combinations** • Ensuring optimal expertise is being used for a lean process in house or through providers • Ensuring appropriate material will be used after finding the right design to avoid costly amendments • Analyzing every factor which may result in product quality and counterfeit issues to have a consistent packaging material with the manufacturer's standard • Considering any layers' feature to deliver an optimal sterilization of the whole package • Addressing the growing use of multilayer films to allow potential adaptations to ensure your package is well combined ***Santiago Beltran,*** *Principal Packaging Engineer,* ***NuVasive***
14:00	**Reviewing criteria to find process management vendors to streamline your operations** • Moving step by step and not rushing phases for choosing a vendor to ensure the best partner is found • Checking all available information about the provider to be able to gain holistic appreciation of what can be

	offered • Analyzing thoroughly working demonstrations to witness how the work will be carried • Defining structured internal investigation for the supplier choosing to have clear opinion on suppliers' abilities • Handling detailed communication to ensure mutual goals are clear ***Speaker TBC***
14:30	**Session reserved for CCL** ***Content TBC***
15:00	Afternoon refreshments and networking
15:30	**Improving tracking and control systems system to have constant updates about global regulations** • Collaborating with supply chain and safety departments to be aware of any potential updates • Upgrading system to track label modifications globally to ensure ease in decision making • Building better system to have a safety signal which notifies products' movements out of the market place • Assessing information criticality to take safety decision to know what features to include in the labeling • Keeping products accurately tracked to ensure you are prepared in case of either USDI or STMI request information ***Michele Goodwin,*** *RA/QA Manager,* ***Entra Health***
16:00	**Session reserved for Schlafender Hase** ***Content TBC***
16:30	Chair's summary and close of conference

	Pharma and Device Packaging and Labeling West Coast **Conference Date: November 29th** **Program Day Two**
08:30	Registration and refreshments
09:15	Chair's opening remarks
09.30	**Exploiting XML software to expedite your label and make content more accessible** • Creating structured content overview for an easy and quick reference to information collected previously • Organizing relevant XML databases to create powerful combinations • Emphasizing flexibility needed to work with FDA different format for a good communication with institutions • Exploring XML use in pharmaceutical labels to appreciate time management benefits • Defining shortcomings in labeling review process to define the need for XML

	Priya Hays, *Technical Writer,* ***Kite Pharma***
10:00	**Session reserved for Videojet** ***Content TBC***
10.30	Morning refreshments and networking
11:00	**Adhering to FDA enforcement to ensure your serialization is compliant and efficient by the deadline** • Using accurately standard numerical identifiers to verify product at package level when verification is requested • Assessing industry readiness against this law's complexity to ascertain first reactions • Understanding actual meaning of the law to be able to prioritize properly company's work • Reviewing what has been done in the past by companies facing a similar major change to find potential action points • Utilizing differently your inventory to manage to update your supply chain ***David Larwood,*** *CEO, President,* ***Valley Fever Solutions***
11:30	**Session reserved for Amplexor** ***Content TBC***
12:00	Lunch and networking
13:30	**Analyzing testing biologics methods for a clear perception of packaging differences between pharmaceutical products and devices** • Addressing important packaging features in pharmaceutical products to readily incorporate different classes • Looking at different timelines in medical devices packaging: stability, integrity systems and components for more accurate analysis on containers • Streamlining company's tactics to deal with tests differences to run a larger number of tests • Handling ASTM standards properly to reach an untroubled distribution • Assessing solutions for different standards scenarios to launch new distribution processes ***Xiaojing Liu****, Assistant Professor,* ***San Jose State University Packaging Faculty***
14:00	**Exploring new MDRs adopted by the European Union to ensure you are not caught unprepared** • Analyzing ever evolving labeling standards to get ahead with your compliance • Increasing awareness of ill-defined criteria to ensure compliance • Discussing new potential software solutions provided by suppliers to deal with European labeling regulations • Building strategies for adverse events data collection to ensure the right delivery to European patients • Creating a global strategy to ensure harmonized data collection and presentation to build accessibility to European market

	John W. Smith, *Director, Regulatory Affairs,* ***Allergan***
14:30	Afternoon refreshments and networking
15:00	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables
Roundtable 1	Session Content TBC ***Roundtable hosted by Perigord***
Roundtable 2	Streamlining process of supplier evaluation and selection ***Rich Horn,*** *Director, Clinical Supplies,* ***Nektar Therapeutics***
Roundtable 3	Optimizing your e-labeling systems for quick access to information ***Keith Schlotthauer,*** *Packaging and Labeling Design,* ***Stryker Neurovascular***
Roundtable 4	Utilizing real time data correctly for choosing your materials and equipment ***Santiago Beltran,*** *Principal Packaging Engineer,* ***NuVasive***
15:45	Chair's summary and close of conference