Accelerating your protein therapeutic through analytical characterization, formulation development, delivery device selection and container closure

What to expect…

• Constructing a rationale approach to protein formulation development
• Developing a plan for oxidation as part of your chemical stability studies
• Innovative trends in monitoring techniques for particulates in 1-5 micron range and the sub 1 micron range
• Case Study: Reversible aggregates – Examining the known and unknown
• Overcoming pipeline difficulties with antibody-drug conjugates
• Examining strategies and assessing FDA requests for industry attention to excipients
• Generating a better understanding of viscosity behavior in high concentration monoclonal antibody solutions
• Quantifying uniformity of components in the injectable device
• Late stage container closure and selection – alignment with your formulation

Featuring a Distinguished Speaker Faculty from Organizations such as:

John Wang, PhD, FAAPS, Group Leader and Principal Scientist, Genentech

Kevin Maloney, Associate Director, Protein Pharmaceutical Development, Biogen Idec

Andrea Ji, PhD, Scientist, Late Stage Pharmaceutical & Processing Development, Genentech

Kavitha Koushik, Manager, Formulation Development, Alvogen

Vineet Kumar, Senior Research Scientist, Preformulation (Biologics), Abbott Laboratories

Sathish Singh, Senior Scientist, MedImmune

Yin Lai, Senior Scientist, Formulation Development, ImClone Systems (Subsidiary of Eli Lilly)

Abizer Harianawala, Director, Formulations, Zalicus

Manvi Hasija, R&D Scientist, BRD, Sanofi-Pasteur

Steve Berkowitz, Principal Scientist, Biogen Idec

Sotirios Koutsopoulos, Research Scientist, Center for Biomedical Engineering, Massachusetts Institute of Technology

Martin Lemmerer, Integrated Biologics Profiling, Novartis

Maria Toler, Principal Scientist, Biotherapeutics Pharmaceutical Sciences R&D, Pfizer

Register by August 10th and Save up to $200. See page 6 for details!
Dear Colleague,

Protein formulation development and how to develop an effective, marketable protein drug is a hugely important area for the pharmaceutical industry. However, there are a great many challenges currently preventing optimal formulation since protein molecules are so difficult to handle ‘at benchside’ and deliver to a patient ‘at bedside’. These plus many other areas need to be carefully dealt with, all the whilst being regulated to be safe for use in humans.

Selecting different formulation compositional elements; such as optimal pH, optimal buffers, optimal excipients, inferring structural chemical, physical and biological stability, ensuring minimal aggregation through effective predictive methods and undertaking novel delivery techniques through efficient early preformulation are just a sample of some the areas in need of focus. This event will look to provide insight into innovative techniques for these dilemmas and technologies being designed with which to predict, screen, test and accelerate formulation development towards license approval. In essence, there is currently no rational approach to develop a protein biotherapeutic, and this forum will seek to provide the information for formulation scientists to construct this.

Best Regards,
Ruel Baird
Conference Producer

Who you will meet

From Market-Leading Pharmaceutical, Biopharmaceutical and Biotechnology Companies:

Vice Presidents, Heads, Directors, Area Leaders and Project Leaders, Principal Scientists Worldwide of:

- (Protein) Formulation Development
- Preformulation (Analytics)
- Formulation R&D Biologics
- Drug Product Development
- BioFormulations Development
- Process Development
- BioPharmaceutical Development
- Pharmaceutical & Analytical R&D
- Biologics Development
- Analytical Sciences
- Biotech Products Development
- BioPhysical Analysis
- Protein Engineering

From Market-Leading CROs, CMOs, Medical/Delivery Device Manufacturers, Analytical Technology Providers:

Vice Presidents, Heads, Directors, Area Leaders and Project Leaders Worldwide of:

- Formulation Development
- Pharmaceutical Services
- Analytical Sciences/Services

Together with:

- Regulatory Bodies

About the Organizer

Pharma IQ, a division of IQPC, provides useful training courses, conferences and expositions for pharmaceutical executives to network and learn the latest pharma business development and trends occurring in organizations today. Pharma IQ focuses on establishing an interactive experience featuring practical, objective, and up-to-date insight from pharma industry leaders.

PS. Don’t miss the highly interactive and informative pre-conference workshops! See page 3 for details!

Sponsorship Opportunities

Sponsorships and exhibits are excellent opportunities for your company to showcase its products and services to high-level, targeted decision makers attending the Protein Formulation Development Summit. IQPC helps companies like yours achieve important sales, marketing and branding objectives by setting aside a limited number of event sponsorships and exhibit spaces – all of which are tailored to assist your organization in creating a platform to maximize its exposure.

For more information on sponsoring or exhibiting at this or upcoming events, please contact Simon Copcutt at 1 (212) 885-2771 or Simon.Copcutt@iqpc.com.

Register by August 10th and Save up to $200. See page 6 for details!
**High-Throughput Screening To Assess Biophysical Properties**

A continuous close interaction of the early stage formulation and discovery focus is needed to ascertain that the development candidate meets the high concentration target the product profile needs. This holds true, especially for novel antibody like molecules, that have much lower probability of success. Examples will be used to show how a continuous feedback engineering can be used to mitigate the risks associated with the selection of an unwanted and/or difficult candidate(s).

*Vineet Kumar, Senior Research Scientist, Preformulation (Biologics), ABBOTT LABORATORIES*

---

**Engineering Better Molecules For Better/Faster Formulation Development**

During candidate selection, limited material is available for biophysical characterization. We assess and pick winners in a high-throughput manner by utilizing automated liquid handling. A high-throughput automation platform enables processing a significantly higher number of samples and analytical runs compared to a conventional setup. Other advantages of this approach are lower sample consumption, flexibility for the analyst, remote monitoring, reduction of lab errors, elimination of redundant work and the ability to trend laboratory activities. By application of automated liquid handling we have established a novel screen that enables us to assess critical biophysical properties such as precipitation behavior, solubility, turbidity, second viral coefficient and viscosity. This screen has been implemented for profiling therapeutic proteins and to pick stable candidates for formulation and purification development.

*Martin Lemmerer, Integrated Biologics Profiling, NOVARTIS*

---

**Assessing The Impact Of A Chemical Modification On A Protein Biopharmaceutical In Terms Of Its Higher Order Structure Using Hydrogen/Deuterium Exchange With Mass Spectroscopy Detection**

Mass spectroscopy (MS) is the key tool in the biopharmaceutical industry for detecting primary structure changes in a protein biopharmaceutical. However, with recent advances in hydrogen/deuterium exchange with mass spec detection (H/DX-MS) and with the commercialization of an H/DX-MS turn-key system, the stage is set where MS can now also play an important role in assessing the impact of these primary structural changes on the high-order structural and structural dynamics of these protein biopharmaceuticals. This presentation will be concerned with the following:

- The basics in conducting H/DX-MS
- Case examples highlighting how this technology can be used in the biopharmaceutical industry
- Present advantages and limitations, and future developments

*Steve Berkowitz, Principal Scientist, BIOGEN IDEC*

---

**Considerations for Pre-formulation Development for a Vaccine Candidate**

In the development of pharmaceutical vaccines, one of the persistent challenges is assuring acceptable stability. Setting specifications for biologics requires a blend of knowledge of the product, regulatory understanding and scientific expertise. There may be challenges, particularly in early phase development, as limited stability indicating assays are available, degradation pathways are unknown, and characterization of the product is minimal. In the development of a pharmaceutical product, speed to market has a great influence on the profitability of that product; how do we ensure that the last patient in a given study is receiving equivalent product to the first. This talk will cover case studies on conducting pre-formulation studies including force degradation and accelerated stability for a vaccine candidate.

*Manvi Hasija, R&D Scientist, BRD, SANOFI-PASTEUR*

---

**Analysing Platform Technologies vs. Tailor Made Formulation Development In The Race To POC**

- Comparing platform development for phase I and beyond versus tailor made
- Can you utilize platform technologies when you are working with a wide range of proteins?
- Analyzing why formulation scientists are using high throughput or platform technologies
- Evaluating alternatives that are available to accelerate development time to POC

*Kevin Maloney, Associate Director, Protein Pharmaceutical Development, BIOGEN IDEC*

---

**Reversible Aggregates – Examining The Known And Unknown**

- Techniques to quantitate and trap reversible aggregates
- Determining the potency of reversible aggregates
- FDA perspective – can they be in the formulation or not?
- What are the regulatory ramifications if an equilibrium exists?

*Sathish Singh, Senior Scientist, MEDIMMUNE*
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00</td>
<td>Registration and Coffee</td>
</tr>
<tr>
<td>8:45</td>
<td>Chairperson's Recap of Day 1 &amp; Day 2 Welcome</td>
</tr>
</tbody>
</table>
| 9:00  | **Particle Characterization of Biologics When Dealing with Limited Sample**  
   Established techniques exist for determining particle content in Biologic formulations, many requiring large amounts of sample. Techniques and approaches will be presented to allow for characterizing particulates in biologic formulations when dealing with limited sample amounts. Characterization of sub-visible and visible particles will be addressed, including intrinsic and extrinsic particulates. Case studies will be presented providing practical examples.  
   **Maria Toler,** Principal Scientist, Biotherapeutics Pharmaceutical Sciences R&D, **Pfizer** |
| 9:45  | **Critical analysis and interpretation of biophysical data in characterization and formulation development of protein therapeutics**  
   Critical analysis, interpretation and understanding of complex data are very important for successful formulation development, structural characterization and comparability assessments of protein therapeutics. At times, contradicting results obtained from chemical and biophysical analysis complicate data interpretation and decision-making. Therefore, a think out-of-the-box approach is necessary to understand results in order to make the best decision. This presentation will discuss case studies that involve (i) interplay of apparent solubility, conformational stability, chemical stability and implications on high concentration protein formulation, (ii) critical considerations in analyzing accelerated stability samples.  
   **Yin Lai,** PhD, Senior Scientist, Formulation Development, ImClone Systems, A WHOLLY-OWNED SUBSIDIARY OF ELI LILLY & CO. |
| 10:30 | Networking Break                                                        |
| 11:15 | **Self-Assembling Peptide Formulations for Drug Delivery**                
   • Designer self assembling peptides  
   • Injectable peptide hydrogel for targeted delivery of small drug compounds and proteins  
   • Self assembling peptide nanovesicles for drug delivery  
   **Sotirios Koutsopoulos,** Research Scientist, Center for Biomedical Engineering, MASSACHUSETTS INSTITUTE OF TECHNOLOGY |
| 12:00 | Networking Lunch                                                         |
| 1:00  | **Understanding Viscosity Behavior In High Concentration Monoclonal Antibody Solutions**  
   • The interaction parameter  
   • The formulation of products with high viscosity  
   • The zeta potential and effective isoelectric points  
   **Devendra ”Davy” Kalonia** |
| 1:45  | **Innovative Trends In Monitoring Techniques for Particulates In 1-5 Micron Range & The Sub 1 Micron Range**  
   • Discussing transitions and oscillator strengths involving f-, g-, and h-states  
   • Identifying the impact on protein formulation  
   • Analyzing the evolution of these particles  
   **Abizer Harianawala,** Director, Formulations, **ZALICUS** |
| 2:30  | Afternoon Networking Break                                               |
| 3:15  | **Biosimilars/Follow On Biologics – The Elephant In The Room**           
   New regulation from the FDA regarding biosimilar development in the North American market has opened the potential for a number of originator companies. Understanding the new guidance and extrapolating how long potential biosimilars would take to develop as well as an understanding of the recent collaborations are of major interest. This session will cover:  
   • Understanding how to interpret the new legislation and take experience from global biosimilars markets  
   • How to conduct optimal analytical characterization of the molecules  
   • The development challenges you stand to face in formulation and how biosimilars are affected by excipients  
   **Kavitha Koushik,** Manager, Formulation Development, **Alvogen**  
   **Siyawosh Moghaddam,** Vice President, **Alvogen** |
| 4:15  | **Late Stage Container Closure And Selection – Alignment With Your Formulation**  
   Big pharma typically do primary container closure selection off the shelf for phase I or II, whereas smaller companies/biotechs will outsource depending on the outsourcing selection. Usually, selection is not based on whether a certain type of vial or syringe exhibits a reduced aggregation with a certain class of protein. Thus, practitioners they can find out down the line that the vial and the stopper or other components are not compatible. This session will provide a detailed discussion in the considerations required when selecting components of containers:  
   • How to make the optimal selection and manage all the component parts  
   • Life cycle selection and risk management factors  
   • Strategies to alter formulation with container, stopper or tip caps for syringes  
   • **Case Study:** Disposable technologies: Being used more and more in final drug closure and having a big impact on the stability of a drug – This discussion will focus on the impacts on the formulation strategy and fill finish manufacturing  
   **Abizer Harianawala,** Director, Formulations, **ZALICUS** |
| 5:00  | Chairperson’s Closing Remarks & End of Summit                            |

**Main Conference Day Two**  
**Wednesday, September 12, 2012**
Register me for: (Email this form to Info@IQPC.com or fax to 646-378-6025)

- Conference
- Please keep me informed via email about this and other related events.
- Check enclosed for $___________ (Payable to IQPC)

Please note multiple discounts cannot be combined.

Venue is to be announced: Please check the website at www.proteinformulationsummit.com for updates and announcements. If you would like to be notified via email as soon as the information becomes available please email iqpc@iqpc.com with the following subject line: "Protein Formulation Development Venue Request".

Please note multiple discounts cannot be combined. A $99 processing charge will be assessed to all registrations not accompanied by credit card payment at the time of registration.

MAKE CHECKS PAYABLE IN U.S DOLLARS TO: IQPC
*CT residents or people employed in the state of CT must add 6.35% sales tax.

---

<table>
<thead>
<tr>
<th>Package</th>
<th>End User Pricing*</th>
<th>Vendor Pricing**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Register &amp; Pay by 7/12</td>
<td>Register &amp; Pay by 8/10/12</td>
</tr>
<tr>
<td>Conference</td>
<td>$799 (Save $200)</td>
<td>$899 (Save $100)</td>
</tr>
<tr>
<td></td>
<td>Register &amp; Pay by 8/10/12</td>
<td>$1,599 (Save $400)</td>
</tr>
</tbody>
</table>

IQPC reserves the right to determine who identifies as an end user or vendor upon registration for an event. Those who are determined a vendor will be denied access to end user pricing.

These prices are featured as a limited time only promotion. IQPC reserves the right to increase these prices at its discretion.

©2012 IQPC. All Rights Reserved. The format, design, content and arrangement of this brochure constitute a trademark of IQPC. Unauthorized reproduction will be actionable under the Lanham Act and common law principles.