November 2014
Volume 2
Annual Conference Overview

## Table of Contents


| | |
|---|---|
| Introduction | 1 |
| Discovery | 2 |
| Modeling and Simulation | 3 |
| Continuous Processing | 4 |
| Green Chemistry | 5-6 |
| Regulatory and Manufacturing | 6-7 |
| Consortia Update | 8 |


# The PD2M Pipeline

## Introduction

### Shekhar Viswanath

Welcome to the PD2M Pipeline volume 2 (2014). In this newsletter, we will cover the highlights of various sessions at the upcoming AIChE National Meeting to be held at Atlanta, GA from Nov 16-21, 2014. PD2M offers 30 oral presentation sessions and one poster at the AIChE National meeting this year. As in the inaugural newsletter published earlier this year, we will highlight relevant sessions of interest in the main themes of pharmaceutical discovery, regulatory topics, green chemistry, continuous processing, modeling and simulation, manufacturing, and talks from various consortia of interest. Our objective is to not only enable the conference attendee to have a valuable and informative conference, but also to provide a useful summary to the folks who are unable to attend the conference this year.

The PD2M talks kick-off with the Plenary session (session 79) on Monday morning (Nov 17, 2014) at 8:30 am. Prof. Samir Mitragotri from UCSB kicks off the plenary with a presentation on advances in Drug Delivery Technologies. Dr. Steve King from AbbVie then presents details on how collaboration Across Drug Substance, Drug Product, and Preclinical Science can improve Drug Development. Prof. Jeff Varner then presents a discussion on utilizing network analysis techniques on complex biological pathways to carry out target selection. Lastly, Dr. Bob Bailey from Amgen will present a biologics-focused talk on Upstream and Downstream Strategies to Actively Control Product Quality Attributes.

If you would like to contribute to AIChE PD2M programming by offering ideas for sessions or chairing existing sessions, please plan to attend the PD2M programming meeting on Tuesday morning (Nov 18, 2014) at 11:15 am in Hilton 201

Please don't forget to attend the PD2M awards ceremony at the Hilton Grand Ballroom D from 6:30 to 9:30 pm on Monday, Nov 17 2014. This well attended ceremony will feature three sponsored awards; notable research in drug development, notable research in drug product development and lastly for research conducted at the drug substance-drug product interface.

# Discovery

## Doraiswami Ramkrishna, Meenesh R. Singh

The Annual AIChE Meeting in Atlanta has numerous sessions comprising papers in various aspects of Pharmaceutical Discovery. They include experimental and computational methods in both Systems Biology and Synthetic Biology. Session 74 entitled Paradigms in Systems Biology begins with a perspective presentation by Zhao in challenges and opportunities in Synthetic Biology, covering novel synthetic biology tools through projects which include discovery issues and engineering of novel biosynthetic pathways for drug discovery and development of genome scale engineering for strain development and cell line creation. It is followed by an in Vivo systems perspective by Lauffenburger of how tissue cells interact with immune systems cells in disease.

Session 149 contains a presentation by Whitehead et al. on biomolecular engineering at the level of DNA sequencing. Application of the methodology is considered to binding of proteins to different Gram-negative microorganisms. Papoutsakis et al. have a presentation in the same session on a quantitative proteomic approach to understand post-transcriptional gene regulation in a stress response network with potential application towards strain development for diverse practical purposes.

Session 265 features a presentation by Gonzales and Peeples on the oxidative capacity of the fungus *Beauveria bassiana* for various applications with respect to its capacity for oxidizing steroids and potential application to the production of drug metabolites.

Session 280 has a focus on high throughput technology and combinatorial techniques. VanDeventer et al. discuss the use of Yeast surface display (YSD) in identifying and improving the properties of proteins for use in diagnostic and therapeutic settings. It is followed by a presentation by Abbaspourrad and Weitz on engineering enzyme by fluidics. A subsequent paper by Woldring et al. discusses the use of YSD for magnetic and fluorescent selection and sequencing of thousands of binding ligands. It also covers the use of an in-house code, Rosetta, and FoldX for high throughput computation of structural and stability metrics of diversified protein mutants to assess side-chain accessibility and stability tolerance.

Session 332 includes a presentation of DeVilbiss et al. that shows the use of cybernetic models to predict gene expression data in inflammatory response from postulating that Macrophage cells maximize TNF-alpha production.

Session 347 is entitled Rational and Computational Techniques begins with a presentation by Ribeiro and Ortiz on the use of computational tools to characterize allostery in Hsp70 towards understanding how signals propagate in this molecule and to better predict the effect of drugs in its function. It is followed by a presentation by Floudas et al. on the molecular dynamics simulations and free energy calculations to design a novel 13-residue peptide which would mimic the HIV-1 binding to both coreceptors, and thus block "universally" the HIV-1 entry. The novel peptide is observed to provide the basis for a new generation of "universal" anti-HIV entry therapeutics. A follow-up paper by Tong Li et al. further delves into the topic of the previous presentation. A subsequent paper by Kathryn Tiller et al. reports on a novel approach for designing antibodies specific for ameloid proteins using molecular interactions that mediate protein aggregation.

Finally Session 467 on application of protein engineering to therapeutics begins with a paper on cell-based immunotherapy, involving the use of living cells to modulate the immune system for combating diseases. A subsequent paper by Sai Reddy discusses Advanced Next-Generation Sequencing (NGS) for large scale analysis of antibody variable gene repertoires.

Pharmaceutical therapeutics and pharmaceutical discovery are represented well in the meeting.

# Modeling and Simulation

## Joe Hannon

Since attending our first AIChE Annual Meeting in 1990, we have had the pleasure to sample sessions from right across the program, with an emphasis ranging from fundamental research, to mixing, simulation, reaction engineering, process development and PD2M. As PD2M appeals to both academicians and practitioners across the spectrum, we have borne both perspectives in mind in writing this article. We also like to pick some sessions and talks that are a little leftfield, taking the opportunity this presents to broaden the mind and bring a fresh perspective.

AIChE is a bustling Annual Meeting, with so many parallel sessions with interesting talks that people rush in and out of rooms after each talk, hoping to catch the ones that appeal most. We always make use of the Personal Scheduler to identify timing or location conflicts and make sure that one of our team gets to hear each talk that we target. The electronic meeting program and now the meeting App make this even easier to do.
Modelling and Simulation talks appear all over the agenda. AIChE is a great place to hear about modeling and simulation as an integrated part of applying the scientific method, alongside experimental work; the papers featuring this approach are far too numerous to list. The picks below are somewhat personal, though several could be highlights of the meeting. We hope that you find this list useful and enjoy the meeting.

| Session # | Title and link to details | Notes |
|---|---|---|
| 63 | Industrial Applications of Computational Chemistry and Molecular Simulation I | A mind broadening choice, to see what is happening in adjacent fields |
| 126 | (126f) Dynamic Feasibility Analysis of Black Box Processes | Looks like an interesting combination of optimization and metamodeling |
| 158 | Tools for Accelerating Pharmaceutical Development | Well; that is what it's all about, isn't it? |
| 203 | A Practical Computational Tool to Predict Formulation and Process Variables during the Development of Spray-Dried Amorphous Solid Dispersions | A presentation by Hovione on a unique and important field of expertise and capability |
| 317 | Simulation and Analysis of Biologically Inspired Chemical Reaction Networks Using Moment Closure | An interesting combination of approaches to tackle complex reaction networks with inherent variability |
| 330 | Process Simulation in the 1960s and 1970s | For historical perspective and to hear about early movers in this field |
| N/a | Evening meeting of US based representatives of organizations involved with SSPC | Modeling plays a significant role in this large Irish led research program and this dinner will show member organizations how to engage with the work |
| 641 | Simulation of Stirred Tank Hydrodynamics Using Mesh and Meshless Methods | For an update on how far this field moved since the early 1990s |
| 650 | Predictive Scale-up/Scale-Down for Production of Pharmaceuticals and Biopharmaceuticals | A favourite session of ours that we hope becomes a regular every year |
| 680 | (680d) Development of a Robust API Crystallization in a Multi-Component Solvent Mixture: Using High Throughput Automation As an Enabling Technology to Develop Comprehensive Solubility Maps | From one of our users, who has built on our templates to view solubility across a sequence of unit operations |

# Continuous Processing

## Martin Johnson

This year's PD2M section of the annual AIChE meeting appears to have several exciting sessions devoted to continuous processing in the pharmaceutical industry. Two sessions are devoted to drug substance synthesis on Monday (session 105) and Tuesday (session 361), and on Wednesday (session 428) one session is devoted to continuous drug product produc-tion.

Topics in Monday's session include a discussion around a multi-step continuous process, as well as presentations on packed catalyst bed reactors, nanofiltration membranes, crystallization, and accumulation and clogging in micro reactors. The first is a presentation by BMS that covers both laboratory development and scale up to pharmaceutical production, and shares results of converting a cryogenic batch process to an ambient flow process (105a). A second presentation by BMS in collaboration with Princeton University using packed bed reactors for enzymatic hydrolysis shows full conversion was achieved in $\tau < 5$ min versus 24 hours in batch (105b). A talk by researchers at Imperial College London presents development of a continuous catalytic Heck coupling and ring closure metath-esis in a PFR combined with continuous cata-lyst recovery by organic solvent nanofiltration (105c). Researchers from The University of Strathclyde will present a continuous antisolvent nucleation unit for generating seed suspensions resulting in improved particle size control (105d). A presentation on continuous reaction with solids in flow will be given by the Jensen group at MIT, describing design strategies for optimizing reaction and avoiding micro-reactor clogging (105e). A related academic talk from the University of Alabama will provide scientific explanations of the inorganic fouling mechanisms for palladium-catalyzed amination in micro reactors (105f).

Topics in the second session on November 18th include startup transition, operating strategy, crystallization, modeling and simula-tion, and membrane purifications. The Barton group at MIT presents dynamic optimization of process startup, where the difficult mathematical problems of non-differentiability and discontinuity are addressed (361a). Engineers at Eli Lilly present a case study in defining acceptable operating space for a CSTR Grignard formation reac-tion (361b). University of Limerick researchers present a complex computational modeling analysis of a cooling and anti-solvent crystal-lization, incorporating particle growth, pri-mary and secondary nucleation, aggrega-tion, breakage, and convection 361c). A collabo-ration between Eli Lilly and UC, Santa Barbara brings a presentation on obtaining pure enantiomers through "continuous preferential crystallization". This includes work covering both continuous processing and modeling applications through the use of population balance models to under-stand parameters in a process that uses wet mills for continuous seed generation, recy-cle streams, and dissolution of nuclei of the undesired enantiomer (361d). Process modeling for continuous Ibuprofen production will be shown by University of Edinburgh. The simulated process includes three PFR reac-tions in series and continuous purification (361e). A second Imperial College London talk describes continuous Roxithromycin purification by multistage organic solvent nanofiltration membrane cascades as an alternative to crystallization or process chromatography. The API is separated from a potential Genotoxic Impurity DMAP with two stage membrane simple cascade (361f).

Drug product has a dedicated continuous processing session as well, which begins Wednesday, November 19,at 8:30 AM. Topics include continuous wet granulation, coating, mixing, PAT with feedback control, and numerical modeling. Merck is present-ing twin screw wet granulation process which includes a complex designed set of experiments to study how PSD, flowabil-ity, density, compactability, tablet strength, and dissolution are impacted by GFL, screw speed, throughput, screw design, and temperature (428a). Rutgers is presenting continuous high shear wet granulation, where they found that rota-tion speed and L/S ratio had significant effects on the granule properties (428b). Stud-ies in continuous coating will be present-ed by Purdue University engineers where they studied how particle axial motion affects inter-particle coating in a continu-ous rotating drum coater (428c). Eli Lilly has two talks in this session, the first of which describes the impact of a variety of mixing phenomena on fully integrat-ed continuous drug product processing. This work is unique in that they quanti-fied mixing which occurs in a tablet press feedframe, reducing the require-ment to achieve complete mixing up-stream (428d). In their second talk, they focus on the numerical modeling to fundamentally increase the observability of the states of the system. The mathematical modeling aids development, and it is an integral component of the control strategy (428f). Chemical engineers from University of Puerto Rico will talk about their eval-uation continuous manufacturing plant performance for the production of tab-lets, making use of SynTQ, SimcaQP, and Simca P+ (428e).

Overall this should be an exciting opportunity to learn about many of the facets of the rapidly maturing element of pharmaceutical processing in continuous drug substance and drug product production. We look forward to seeing you in Atlanta.

# Green Chemistry

## Masano Sugiyama

Given the lack of green chemistry talks related to pharmaceutical development at this year's national conference, a perspective on the development of Green Chemistry initiatives at BMS has been provided. The pharmaceutical industry recognizes the importance of green chemistry and engineering. Fifteen member companies work together in the framework of The American Chemical Society Green Chemistry Institute's Pharmaceutical Roundtable to integrate green and sustainable engineering in the pharmaceutical industry. The Roundtable has advanced the adoption of green chemistry on multiple fronts by funding grants in research areas of interest and highlighting new technologies to inform readers and push green chemistry to the forefront of discussion. Moreover, it has generated multiple tools that have been instrumental to the discussion of green chemistry from the reagent selection guide, including the Process Mass Intensity (PMI) and Life Cycle Assessment (LCA) Calculators that are freely available to the public.

Pharmaceutical companies are encouraged to join the Roundtable and build internal teams to promote green chemistry awareness and contribute to the initiatives led by the Roundtable. The Green Chemistry Team (GCT) in Chemical Development at Bristol-Myers Squibb was founded in 2008 and officially joined the Roundtable in 2011 to increase green chemistry awareness and provide resources to the chemistry and engineering communities within the company. As part of its recent efforts, the GCT at Bristol-Myers Squibb has worked on tracking and initiating changes early in chemical development to integrate green chemistry design principles in the development and commercialization of new products.

Tracking Metrics

The main tool used at BMS to integrate the principles of green chemistry in chemical development is the Process Greenness Scorecard – an internally-developed calculator that allows quantitative comparison between various processes through detailed analysis of multiple factors such as PMI, solvent type, waste, emissions, number of transformations and isolations, as well as a careful assessment of process safety. Safety is examined in terms of process hazards, explosion potential, runaway potential, and explosion hazards. Upon completion of a campaign and/or at key project milestones, project teams scrutinize the process, complete the Greenness Scorecard and meet with the GCT to identify areas for improvement and discuss potential solutions. This workflow fosters the integration of green chemistry principles in chemical development and drives improvement.

Raise Awareness and Recognition

The GCT organizes an Annual Green Chemistry Symposium where external guests from chemistry, engineering and related fields speak on green chemistry and engineering. Previous speakers include professors discussing their research, colleagues in the pharmaceutical industry, and government officials from the EPA. In addition, the GCT presents an Annual Green Chemistry and Engineering Award sponsored by the Chemical Development Department at BMS for internal projects or initiatives that advanced the practice of green chemistry and engineering with a sustained impact on future drug discovery, development, or manufacturing. Past award winners vary from project teams that accomplished large improvements in sustainability to teams that implemented operational changes leading to greener plant operations.

Provide tools and Resources

The GCT maintains an internal site that provides resources for green chemistry and engineering tools, including a database compilation of green reactions organized by type of transformation to facilitate search as well as links to relevant articles. Other resources on the site include the PMI and LCA calculators, a solvent selection guide and a reagent selection guide, as well as links to tools provided by the ACS GCI Pharmaceutical Roundtable and the EPA. The PMI and LCA calculators allow for convergent multi-step processes comparing parameters such as mass intensity and environmental live cycle information (e.g., carbon foot print). Both the solvent selection guide and the reagent selection guide the choice of solvents and reagents based on their health, safety and environmental impact. These tools allow scientists to better evaluate different processes and provide greener alternatives for consideration.

At BMS, the GCT fosters a culture of green process development with an emphasis in tracking metrics, raising awareness, and providing tools to the scientific community. There is every incentive for members in the pharmaceutical industry to pursue the principles of green chemistry and engineering while advancing innovation if continued progress towards a sustainable practice of chemistry and engineering is our goal.

# Catalyzing Innovation in Green Pharmaceutical Science & Engineering

**Chirstiana Briddell**

This July 14-16 in the Washington D.C. area, the ACS Green Chemistry Institute® will host the 19th Annual Green Chemistry & Engineering Conference. The premiere sustainable innovation conference, GC&E brings together a range of industries, research areas, and interest groups in a three-day event with five concurrent tracks, a poster session, receptions, and green expo.

This year's conference will feature sessions of particular interest to pharmaceutical scientists and engineers including "Sustainable Separation Processes" and "Continuous Processing as a Green Enabler". Additionally, the ACS GCI Pharmaceutical Roundtable will host a full day session titled, "The Next 10 Years of Pharmaceutical Green Chemistry."

Call for papers opens January 15, 2015 and closes March 31, 2015. We encourage members of PD2M to submit papers and participate in this event. More information can be found at www.gcande.org.

# Regulatory and Manufacturing

**John Lepore, Kevin Seibert, Tim Watson, Dan Hallow**

There are several exciting invited speakers presenting at the PD2M plenary session on Monday November 17th at 8:30 am. Much of the principles by which control strategy is defined and justified can have significant regulatory implications.

On Monday evening, a session devoted to post-launch process improvements contains several talks focused on some of the challenges with post-approval modification, including a presentation from BMS emphasizing the use of a design space to make post-approval process changes (207c), and a presentation from Abbvie discussing the integration of multiple platform technologies to support validation activities for a drug substance at their Sligo manufacturing site (207f).

Monday night will also bring a QbD roundtable discussion with industry leaders and the presentation of the annual PD2M awards.

Tuesday morning session 238 looks to have a number of very good presentations with significant regulatory implications based on the outputs of these studies. Merck (238a) will be presenting a case study looking at the risk assessments associated with a crystallization unit operation and the resulting development studies that were driven by these risk assessments. BMS (238b) will be sharing a case study of leveraging Monte Carlo tools to estimate process performance given a defined control strategy that leverages historical data in conjunction with process models. Eli Lilly (238c) will be sharing a case study in developing the regulatory submission data for PARs and multivariate interactions using process models for a small molecule synthesis, and Abbvie (238d) will present their development of a model-based process control strategy in and API manufacturing setting. Lastly, GSK (238e) will be sharing their experience in genotoxic starting material control strategy through the use of kinetic and mixing studies, a hot topic for regulatory concern.

(Continued on next page)

Session 361 on Tuesday afternoon focuses on the application of continuous processing to the manufacture of drug substance. All of the presentations should have regulatory implications with respect to the understanding and operating of continuous processes in the pharmaceutical industry, as well as the linkage of process models to the generation of data. The inclusion of model generated data in a regulatory submission will be of keen interest and is a key element of many of the presentations this year. Of note are several presentations including a presentation from MIT (361a) which will focus on optimally starting up a continuous process, Eli Lilly (361b) who will be sharing their experience in the developing of an operational and control strategy for executing a continuous Grignard reaction in a CSTR infrastructure, and lastly investigators from the University of Limerick (361c), Eli Lilly (361d), and the University of Edinburgh (361e) all of whom will be sharing experience in developing models for describing continuous processes.

This theme of integration of continuous process development, modeling, and the possible regulatory implications will be echoed in a session on Wednesday morning (428) with an emphasis on drug product manufacturing. While the session is packed with very good presentations, of note for those interested in regulatory considerations is presentation from University of Puerto Rico (428e) discussing the implementation of Process Analytical Technologies into a closed loop control system, and a presentation by Eli Lilly (428f) involving the use of mathematical models to aid in developing a continuous drug product manufacturing process.

"Mixing Scale-Up/Scale-Down Issues in Pharmaceutical and Biopharmaceuticals Processes" (#451) will cover a few talks related to always relevant discussion on mixing issues for pharmaceutical and biopharmaceutical processes including some crystallization and bioreactor examples.

On Wednesday session 486 has several talks covering topics around formulation and process design. Of note is a presentation by Pfizer (486e) studying the multivariate impact of API variability, excipient variability and process parameter variability to aid in a Quality by Design based development of a drug product.

Wednesday afternoon and evening include several sessions emphasizing the Quality by Design based principles used in process development. This includes session 527, highlighting a diverse set of presentations focusing on QbD and the development of drug release and dosage systems, and session 585 which highlights several studies implementing process analytical technologies (PAT) in both commercial settings as well as development laboratories and spanning applications in both drug substance as well as drug product platforms.

Thursday also includes several sessions with potential regulatory implications. Of note is session 668 with presentations applying QbD approaches to drug product processes. A presentation from the National Technical University of Greece (668d) promises to share their experience in mapping a design space for oral pharmaceutical drugs.

To finish out this exciting week of technical exchange, session 739 includes several presentations focused on the scale-up of pharmaceutical manufacturing processes with an emphasis on leveraging a QbD approach to the effort, all with potential regulatory challenges. Several notable presentations include a study from BMS (739b) which focuses on identification of critical process parameters, proven acceptable ranges, and executing designed experimental sets through the use of PAT and conventional analytical tests for characterization. Additionally, a study from Rutgers University (739c) describes the development of a closed loop control system integrating model predictive control with traditional PID based control for a drug product manufacture. Additionally, in a collaborative effort from RCPE, GSK and MG2, paper 739d describes the successful scale-up and execution of a DOE to confirm the consistency of critical process parameters and minimal impact from critical material attributes on a low fill-weight inhalation product in a capsule formulation.

As you can see, the programming for this year will offer some excellent opportunities to learn about a broad range of efforts at the interface of science, engineering, and regulatory implementation. We look forward to your joining us!

# Consortia Update

## Steve Baric

An emerging development amongst large and small pharmaceutical companies is the establishment of new collaborations on technologies for process development that exist in a pre-competitive workspace. This trend has recently been given momentum by the Innovation & Quality (IQ) Consortium to focus members on the potential holistic benefits through partnerships in cross-company collaborations as well as incorporation of academic and vendor partners, and potentially support by government funded research institutes. The scope of this initiative by the IQ Consortium has been focused on enabling technologies in process development and separated into five main categories: (1) automation, (2) process analytical technology (PAT), (3) flow chemistry, (4) modeling and (5) crystallization/isolation technologies. The consortium has recognized that such partnerships have recently been formed and achieved success partnership developments. This year's AIChE Annual Meeting has a session within the PD2M Forum dedicated to the discussion of these types of collaborations.

The session, "Pre-Competitive Collaborations in the Pharma Industry: Perspective and Opportunities", Chaired by Jean Tom (BMS) and Joe Hannon (Scale Up Systems) is being held in Rom 202 at the Hilton on Tuesday, November 18th and runs from 8:30 AM to lunch time.

This session (277) features presentations and a panel discussion about opportunities and success stories involving pre-competitive collaboration in the pharmaceutical industry. Presentations give perspective on the global picture for funding, including Europe, and the criteria involved for successful applications and collaborations, whether driven by academia, industry or regulators.

(277a) Ensuring Success of Broad Industrial/Academic Collaboration by Brian Glennon (UCD) and Jon O Halloran (SSPC)

(277b) Exploring Opportunities for Information Exchange and Mutual Development of Enabling Technologies by Srinivas Tummala (BMS), Kevin D. Seibert (Eli Lilly) and Margaret Faul (Amgen)

(277c) The Center for Pharmaceutical Development (CPD) – an I/U CRC for Late-Stage Pharmaceutical Development by Andreas S. Bommarius (Georgia Tech)

(277d) Collaborative Development of an Auto-Sampling Probe for HPLCby Joel M. Hawkins (Pfizer), Daniel Hallow (Janssen) and Leen Schellekens (Mettler-Toledo)

(277e) Systems-Based Pharmaceutics - An industrial pre-competitive alliance by Salvador García-Muñoz (Eli Lilly)

To highlight a recent success story of such a partnership (277d), one could point to the collaboration between Pfizer, Johnson & Johnson and Mettler Toledo (and later Merck and Bristol-Myers Squibb) to develop an automated sampling device for lab scale reactions (EasySampler®). This technology was originally conceived and championed within Pfizer R&D but required a vendor such a Mettler Toledo to impart its mechanical and software expertise to prefect and generates a viable instrument. Two key elements that made this partnership a success for all the partners: (1) This technology lies in a pre-competitive space, as none of the Pharmaceutical Companies have interest in developing their own automated sampling tool, and (2) there is the potential to bring a holistic benefit to the industry partners, who help drive a product toward the key specifications and functionality, and also to the vendor, who is able to leverage these early adopters perspectives and prototype-testing develop a product that immediate and broad appeal in process development. These are the types of opportunities and partnerships the IQ consortium would like to recognize and catalyze to bring more advancement to pharmaceutical process development.

Whether you are a member of one of these consortia, interested in joining, or just interested in the technologies being developed in cooperation with academia and industry, I encourage you to participate in this session, the panel discussion and the follow-up actions that may include collaboration discussions and submission of proposals for funding.

AIChE
The Global Home of Chemical Engineers

**American Institute of Chemical Engineers**

**Pharmaceutical Discovery, Development, and Manufacturing Forum (PD2M)**



**If you have any questions or would like to contribute to the newsletter—email** viswanathsh@lilly.com