2nd Annual | May 21-22, 2014

Formulation and Drug Delivery

Strategies for Enhancing Solubility, Bioavailability and Faster Product Design and Development

Register Now

Conference Highlights:

- Hear Case Studies from AstraZeneca, BMS, Cempra, Cubist, Merck, Novartis, Pfizer and More!
- Learn Strategies on Improving Bioavailability, Preformulation, Risk Assessment & Mitigation
- Apply Enabling Technologies for Enhancing Solubility and Delivery
- Gain Knowledge on How to Reduce the Formulation & Process Development Timelines
- Participate in Interactive Short Course on Nanotechnology for Enhancing Bioavailability of Poorly Soluble

FEATURED PRESENTATIONS:

Solithromycin, a Fourth Generation Macrolide, the First Fluoroketolide in Development for Use in Oral and Intravenous Dosing Formulations for Adult and Pediatric Use

Prabhavathi Fernandes, Ph.D., President and CEO, Cempra, Inc.

Cohesion Reduction of Fine Pharmaceutical Powders via Surface Modification

Rajesh N. Davé, Ph.D., Distinguished Professor of Chemical, Biological and Pharmaceutical Engineering; Site Director, NSF-ERC on Structured Organic Particulate Systems, New Jersey Institute of Technology

7th Annual | May 22-23, 2014

Efficient Process Chemistry

Successes and Challenges in API Development

Conference Highlights:

- Thinking Ahead in Route Development
- Process Development and Scale-Up Considerations
- More Process Chemistry Case Studies

FEATURED PRESENTATION:

Telaprevir Route Development Retrospective

Gerald Joseph Tanoury, Ph.D., Senior Scientific Fellow, Process Chemistry, Vertex Pharmaceuticals

Keynote Speaker:

Catalyzing Translational Innovation

Christopher P. Austin, M.D.

Director, National Center for Advancing Translational Sciences, National Institutes of Health

May 21-23, 2014

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Boston, MA

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Conference-at-a-Glance

Tuesday, May 20	Pre-Conference Short Courses* - Animal Models Of Pain: Progress And Challenges - Introduction To Drug Metabolism And Its Role In Drug Toxicity			- Nanotechnology for Enhancing Bioavailability of Poorly Soluble Drugs - Metastatic Tumor Models: Technology and Applications - Safety Testing for Biological Drugs and Vaccines	
Wednesday, May 21	Tumor Models for Targeted Therapy	Imaging in Oncology	Preclinical Drug Safety	Formulation & Drug Delivery	Targeting Pain
	Keynote Speaker: Catalyzing Translational Innovation **Christopher P. Austin, M.D.** *Director, National Center for Advancing Translational Sciences National Institutes of Health*				
Thursday, May 22	Tumor Models for Targeted Therapy	Imaging in Oncology	Preclinical Drug Safety	Formulation & Drug Delivery	Targeting Pain
	Tumor Models for Cancer Immunotherapy	*In vitro* Tumor Models	Epigenetics Screening	Efficient Process Chemistry	
	Dinner Short Courses* - Refining API Process Development for Efficiency			- How To Best Utilize Organotypic 3D Cell Cultures Assays in Oncology - Computational Modeling of Cancer Genomics	
Friday, May 23	Tumor Models for Cancer Immunotherapy	*In vitro* Tumor Models	Epigenetics Screening	Efficient Process Chemistry	

** Separate registration required.*

About the Conferences

After spending 12 years in Philadelphia, the World Pharma Congress is moving to Boston and welcoming the *Formulation* and *Process Chemistry* conferences into its fold. Boston is buzzing with new findings and technologies that can potentially revolutionize the way in which traditional preclinical drug discovery is done. Here are some reasons why you don't want to miss joining us in the Pharma Hub of Boston!

- This is one of the few events that focuses on preclinical efforts targeted towards early discovery, screening, drug delivery and scale-up
- It brings together a diverse group of scientists working in biology, pharmacology, formulations and process chemistry to facilitate active brainstorming
- Its well represented by people from both industry and academia, leading to active networking and collaborations
- Pre-conference and evening short courses offer an opportunity for attendees to interact with experts in an interactive and informal setting
- Leading technology and service providers offer insights on the latest tools and services and how they can be best utilized
- Informative interactive roundtables, panel discussions, and poster sessions offer more networking opportunities

Keynote Speaker:

Catalyzing Translational Innovation

Christopher P. Austin, M.D.
Director, National Center for Advancing Translational Sciences
National Institutes of Health

The multi-stage and multifaceted translational spectrum is poorly understood, and the current research ecosystem is operationally not well suited to the distinct needs of translation. As a result, biomedical science is in an era of unprecedented accomplishment without a concomitant improvement in meaningful health outcomes, and this is creating pressures that extend from the scientific to the societal and political. To meet the opportunities and needs of translational science, NCATS was created as NIH's newest component in December 2011, via a concatenation of extant NIH programs previously resident in other components of NIH. NCATS focuses on disease-agnostic issues by acting as a catalyst and bringing together the collaborative teams necessary to develop new technologies and paradigms to improve the efficiency and effectiveness of the translational process. This talk will focus on several programs in the NCATS portfolio that are proving to be successful new models in navigating the translational landscape. The presentation will highlight systems toxicology and preclinical development efforts with a focus on the Tissue Chips for Drug Screening Program and the Tox21 Consortium.

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Short Courses*

May 20, 2014 2:00-5:00 pm

SC3 - Nanotechnology for Enhancing Bioavailability of Poorly Soluble Drugs

Chair:

Shaukat Ali, Ph.D., Technical Support Manager, BASF Corp.

Instructors:

Navnit Shah, Ph.D., President & CSO, Kashiv Pharma

Lipa Shah, Ph.D., Principal Scientist, Chemical and Pharmaceutical Profiling, Novartis Institutes for BioMedical Research, Inc.

Michael Perlman, Ph.D., Senior Scientist II, Millennium Pharmaceuticals

Salin Gupta Patel, Ph.D., Associate Principal Scientist, Nanoparticles Technology Development Team Lead, Merck Research Labs

A significant number of new chemical entities (NCEs) are practically insoluble and thus, the industry is struggling to find solutions by adapting the non-conventional innovative and cost effective technologies in development of these molecules. This workshop will be aimed at understanding the significance of nanotechnology in formulation development and its role leading to enhance solubility and bioavailability of drug candidates.

Topics to be Covered:

- Amorphous dispersions and polymeric nanoparticulates
- Liquid dispersions, especially, lipid and surfactant based self emulsifying
- Nano-emulsifying systems (SEDDS/SNEDDS)
- Excipients' role in design of robust dispersive systems and maintaining supersaturation
- Effects of particle size on API stability and performance
- Factors influencing the bioavailability of dosages

May 22, 2014 6:00-9:00 pm *(Dinner will be served)*

Current Trends in Crystallization and Polymorphism: Experiment and Prediction

Part of Property-Based Drug Design Conference

Instructors:

Terry Richard Stouch, Ph.D., President, Science for Solutions, LLC

Sarah L. Price, Ph.D., Professor of Physical Chemistry, Department of Chemistry, University College London

Susan M. Reutzel-Edens, Ph.D., MRSC, Senior Research Advisor, Small Molecule Design & Development, Eli Lilly and Company

Denette Murphy, Ph.D., Principal Scientist, Drug Product Science and Technology, Bristol-Myers Squibb Co.

Reproducible production of crystal forms is a serious issue endemic in pharmaceutical development. The current state of the art in prediction of crystalline form and polymorphs will be discussed. Latest experimental approaches of crystallization will be reviewed.

Topics to be Covered:

- Crystal structure prediction
- Polymorphism
- Experimental approaches
- Case studies

**Separate registration required*

"Good opportunity to interact with industry."

- Graduate Student, Texas A&M University

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Tuesday, May 20, 2014 • 9:00am-12:00pm

Genome Editing Technologies and Applications

Targeted Genome and Epigenome Editing Using Engineered CRISPR and TALE Technologies

J. Keith Joung, M.D., Ph.D., Associate Chief of Pathology for Research; Associate Professor of Pathology, The Jim and Ann Orr MGH Research Scholar, Molecular Pathology Unit, Center for Cancer Research, Massachusetts General Hospital

Targeted genome and epigenome editing technologies have recently emerged as important tools for biomedical research and as potential reagents for therapies of gene-based diseases. In this talk, I will present our recent work on the clustered regularly interspaced short palindromic repeat (CRISPR) RNA-guided nuclease platform for introducing targeted genome sequence alterations, including discussion about the latest specificity improvements developed by our group. I will also describe the creation and validation of new technologies for modifying specific epigenomic marks on histones and DNA that can be used to induce targeted alterations in endogenous human gene expression. Taken together, these methodologies provide transformative tools for understanding human biology and offer promising pathways forward for developing therapies based on targeted alterations of gene sequence and expression.

Novel Tools for Cell-Based Screening With Mixed Populations of Isogenic Wild-Type and Mutant Cell Populations

Ranjit S. Bindra, M.D., Ph.D., Assistant Professor, Departments of Therapeutic Radiology & Experimental Pathology, Yale School of Medicine

Cell-based screening is now a common approach to identify novel compounds and genes which regulate key biologic processes in cells. Live cell growth tracking is an especially useful tool for synthetic lethal screens, although current approaches are limited by the requirement for cell lysis, fixation and/or highly specialized imaging techniques. We recently developed a novel system to fluorescently label cell lines for use in screening assays. High expression levels of many fluorescent proteins without nuclear localization can be toxic in cells, and it can adversely affect the ability of automated cell identification programs to discriminate individual cells. To address these two potential issues, we engineered fusion fluorescent proteins which contain modified FK506- and rapamycin-binding protein (FKBP12) destabilizing domains (dd) on their N-termini, and nuclear localization signals (NLSs) on their C-termini. The FKBP12 dd is unstable in the absence of high-affinity ligands, such as rapamycin and a biologically inert derivative, Shield1. The addition of Shield1 blocks the destabilizing effect of the N-terminal domain dd. Thus, fluorescent protein expression can be induced at specific times by the addition of ligand. Fluorescence is localized to the nucleus by the NLS, which facilitates the identification of individual cells using imaging algorithms. We created fusion proteins for blue, yellow, and red fluorescent proteins (referred to as ddBFPnls, ddYFPnls and ddRFPnls, respectively).We chose to modify these specific fluorescent proteins because they have minimally overlapping fluorescence excitation and emission spectra. This particular feature makes them amenable for use in combination to identify and track multiple unique cell populations. We confirmed that multiple cell lines stably expressing ddBFPnls, ddYFPnls and ddRFPnls could be identified and counted in 384- and 96-well microplates, at a range of cell densities and timepoints, using several different imaging platforms. In addition, mixed populations of isogenic cell lines harboring key mutations were obtained from Horizon Discovery and tested with our fluorescent marking system. These fluorescent marking tools will be useful for researchers interested in cell-based screens, and they likely can be used for simultaneous cell tracking of multiple unique populations *in vivo*.

X-MAN Cell Lines – Enabling Translational Research

Chris Lowe, Ph.D., Director, R&D, Cell Line Engineering, Horizon Discovery

Technological advances continue to improve the affordability of whole-genome sequencing and drive the recent successes in human genetics, identifying genes responsible for Mendelian diseases and unraveling the mutations that predispose individuals to common complex diseases. However, identifying the associated mutations is only the first step in the therapeutic pathway. Understanding the involvement of a mutation in a disease or therapeutic pathway remains a challenge and has been hampered by the lack of suitable *in vitro* tools.

We have used rAAV- mediated homologous recombination, a proprietary part of Horizon's GENESISTM platform (which consists of rAAV, ZFN and CRISPR), to generate suites of isogenic cell lines, carrying specific endogenous mutations in genes such as KRAS, EGFR and PIK3CA, as well as endogenous reporters utilizing NanoLuc luciferase, a small enzyme engineered for optimal performance as a luminescent reporter, to investigate the roles of specific genes and mutations in response to therapeutic agents and demonstrate their utility in functional genomics and high-throughput screening.

For more information on this FREE event please click here.

"Great job by short course speakers, good forum, and relaxed atmosphere."

- Senior Principal Scientist, Drug Safety, Pfizer, Inc.

We look forward to seeing you in Boston! If you have questions about the conferences, please contact

For Formulation & Drug Delivery:

Nandini Kashyap
Conference Director
nkashyap@healthtech.com

For Process Chemistry:

Anjani Shah, Ph.D.
Conference Director
ashah@healthtech.com

2nd Annual

Formulation and Drug Delivery

Strategies for Enhancing Solubility, Bioavailability and Faster Product Design and Development

WEDNESDAY, MAY 21

7:00 am Registration and Morning Coffee

IMPROVING BIOAVAILABILITY WITH PHARMACEUTICS & FORMULATION STRATEGIES

8:00 Chairperson's Opening Remarks

Geeti Gangal, Ph.D., Principal Scientist, Chemical and Pharmaceutical Profiling, Novartis Institutes for Biomedical Research, Inc.

8:05 FEATURED PRESENTATION: Cohesion Reduction of Fine Pharmaceutical Powders via Surface Modification

Rajesh N. Davé, Ph.D., Distinguished Professor of Chemical, Biological and Pharmaceutical Engineering; Site Director, NSF-ERC on Structured Organic Particulate Systems, New Jersey Institute of Technology

Fine powders due to high cohesion pose great challenge to pharmaceutical industry because of problems such as, agglomeration, poor flowability, electrostatic charging and low bulk density. Dry coating based surface modification as a predictive, model-based approach is presented to mitigate these problems, leading to the improvements in flow, fluidization, dispersion, and bulk density. A bulk property based 2-D phase-map is also proposed to help make manufacturing decisions regarding the formulation strategy for solid pharmaceutical dosages.

8:35 Impact of BDDCS Compound Classification on Oral Absorption and the Need for Influx Intestinal Transporter: Statins/ACE Inhibitors as a Case Study

Ayman El-Kattan, Ph.D., Associate Research Fellow, Pharmacokinetic Dynamics & Metabolism, Pfizer, Inc.

Some statins/ACE inhibitors have low intestinal permeability with usually poor fraction of absorption (fa<<80%). Based on BDDCS classification, these compounds are class III and IV. In this presentation, we discuss: 1) The influx intestinal transporters that facilitate the absorption of statins/ACEi including review of structure, SAR/clinical relevance; 2) The impact of food and pharmacogenomics on statins/ACEi absorption; and 3) The use of prodrug as an effective approach to overcome poor oral absorption.

9:05 Simulating the Gastro-Intestinal Tract to Understand Drug Behavior – How Close Do We Need to Go?

Anette Müllertz, Ph.D., Associate Professor, Pharmaceutical Design and Drug Delivery, Department of Pharmacy, University of Copenhagen

Depending on the drug and the dosage form in question, different conditions or events encountered during transit of the gastro-intestinal tract will be determining the absorption of the drug. Therefore one should carefully consider how to develop an *in vitro* assay that will predict the behavior of specific dosage forms. In some cases simulations of the stomach will be of utmost importance, whereas this is not important in other cases. Likewise the digestion processes have to be taken into account for some dosages forms. These factors should be considered when developing an *in vitro* model for development of oral drug products.

9:35 Coffee Break in the Exhibit Hall with Poster Viewing

PREFORMULATION FOR RISK ASSESSMENT & MITIGATION

10:20 Risk-Based Approach to Exploratory Drug Product Development

Madhushree Gokhale, Ph.D., Senior Research Investigator, Drug Product Science &Technology, Bristol-Myers Squibb Co.

An integrated risk-based approach to understand material (form) risks, chemical stability risks, delivery risks and processing risks during early stages of drug product development not only provide a robust design space but also lead to focused drug product development and risk mitigation plans. This talk will highlight use of high-throughput screening techniques, *in vitro*, *in silico*, *in vivo* tools and mini-piloting tools, as well as case studies to showcase integrated risk-based approach in early drug product development.

10:50 What You See May NOT be What You Get— Why Dissolution Testing May be an Unreliable Predictor of in vivo Success

Robert A. Bellantone, Ph.D., Associate Professor, Division of Pharmaceutical Sciences, Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University; President, Physical Pharmaceutical LLC

For poorly soluble drugs and new oral drug delivery strategies, compendial *in vitro* dissolution methods may not provide data relevant for predicting whether a formulation will work successfully *in vivo*. This talk will discuss dissolution-absorption and excipient-solubility relationships, which *in vitro* data aremost relevant for different situations, and why existing methods may not provide the needed data. In addition, some new methods to obtain relevant *in vitro* data will be discussed.

Sponsored by DRGT Druggability Technologies

11:20 Disadvantaged Drugs Turned into Super APIs with Expanded Clinical Utility

Gabor Heltovics, CEO, DRGT

The continuous flow Super-API technology delivers significant pharmacological improvements for compounds where earlier tmax, higher Cmax and higher exposure can lead to clinically meaningful benefit. Disadvantageous food effect can also be reduced or eliminated by the technology due to the novel structure of the developed Super-APIs.

11:50 How HIGH Can You Get? – The Use of *in vitro* Data to Reduce Animal Experiments

Geeti Gangal, Ph.D., Principal Scientist, Chemical and Pharmaceutical Profiling, Novartis Institutes for Biomedical Research, Inc.

Cocrystals, nanosuspension, microemulsion and amorphous Solid dispersion are the various techniques that are commonly utilized to manage solubility issues of the poorly water soluble drugs. *In vitro* tools like pBDDCS, Q-plus and Gastroplus have been used in the literature for the compound classification and assessing the risk associated in the development. However, together these *in vitro* tools can be used as powerful guidance to pick the best formulation that would work for your compound and can lead to reducing animal experiments.

12:20 pm Is it Crystal Clear? Stability and Performance Prediction for Amorphous Pharmaceuticals

Sunny P. Bhardwaj, Ph.D., Senior Scientist, Basic Pharmaceutical Sciences, Merck & Co.

Majority of new drug candidates under development are poorly water-soluble. The amorphous state is of considerable interest since it confers higher apparent solubility and faster dissolution than its crystalline counterpart. However, being the thermodynamically unstable form, it runs the risk of crystallization leading to the loss of solubility advantage. In this presentation, we will discuss different approaches to predict the solid-state and solution state physical stability of the amorphous state with case studies.

12:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:30 Session Break

ENABLING TECHNOLOGIES FOR ENHANCING SOLUBILITY AND DELIVERY

2:00 Chairperson's Remarks

Rajesh N. Davé, Ph.D., Distinguished Professor of Chemical, Biological and Pharmaceutical Engineering; Site Director, NSF-ERC on Structured Organic Particulate Systems, New Jersey Institute of Technology

2:05 Novel Approach of IV Formulation Development of Solithromycin, a Fourth Generation Macrolide Antibiotic

Sara Wu, Ph.D., Director, Product Development, Cempra, Inc.

Solithromycin is a fourth generation macrolide, the first fluoroketolide antibiotic in Phase III clinical trials for Community Acquired Bacterial Pneumonia. The challenges faced during the development of the intravenous formulation of solithromycin will be presented. Optimization of the intravenous formulation to achieve the dosing goal while providing acceptable solubility and local site tolerance relied on an *in vitro* dynamic precipitation model, rabbit ear-vein irritation model and the Phase I clinical results on local tolerance.

2nd Annual

Formulation and Drug Delivery

Strategies for Enhancing Solubility, Bioavailability and Faster Product Design and Development

2:35 Microfluidics: A New Platform for Early Stage Formulation Development

Sabiruddin Mirza, Ph.D., Sr. Research Associate, School of Engineering & Applied Science, Harvard University

Early formulation development is a significant challenge for the pharmaceutical industry, primarily because of the lack of drug materials available at this stage. Microfluidics, an advanced technology that combines the use of tiny volumes of materials with precisely controlled experimental conditions, opens new perspectives in screening and development of clinical trials materials. This talk will highlight the utility of microfluidic platforms in aiding formulation optimization of difficult-to-deliver APIs at the early stage of development.

3:05 Nano Suspension: Why, How & the "Golden Syringe"

Lieyu (Richard) Hu, Ph.D., Scientist, Pharmaceutical Sciences, Cubist Pharmaceuticals, Inc.

A major challenge hindering the development of new chemical entities is low aqueous solubility, limiting formulation and delivery options, in particular intravenous administration. Nanosuspensions, which consist of pure crystalline drug particles stabilized with surface modifier(s) in aqueous media, offer an attractive means of addressing such development challenges. Nanosuspensions can be tailored to enable drug release in a controlled fashion to meet the needs of patients. This talk describes the preparation, characterization, and applications of such nanosuspensions.

3:35 SELECTED POSTER PRESENTATION: A Fast and Reliable Empirical Approach for Estimating Solubility of Crystalline Drugs in Polymers for Hot Melt Extrusion Formulations

Samuel Kyerematenga, Ph.D., Formulation Scientist, Global Pharmaceutical Sciences, AbbVie Deutschland GmbH & Co. KG

Data on solubility of crystalline drug in polymers play a crucial role in formulation and process development of amorphous solid dispersion (ASD). Currently this data is not widely utilized within the pharmaceutical industry because generating such data is very challenging and time consuming. Our work introduces a novel and fast analytical approach for generating solubility data based on an empirical algorithm which can be applied in designing ASD for maximum drug load and physical stability.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

» 5:00 PLENARY KEYNOTE PRESENTATION: Catalyzing Translational Innovation

Christopher P. Austin, M.D., Director, National Center for Advancing, Translational Sciences, National Institutes of Health (Click here for details)

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

7:00 Close of Day

THURSDAY, MAY 22

7:30 am Interactive Breakout Discussion Groups with Continental Breakfast

Topic 1: Why Can't We Bring More Solid Dispersions to Market?

Moderator: Robert A. Bellantone, Ph.D., Associate Professor, Division of Pharmaceutical Sciences, Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University; President, Physical Pharmaceutical LLC - Biography

- We have been studying solid dispersions for approximately five decades, why do we still not know how to control them?
- What do we need to learn before we can make these systems work for more drugs?
- Is there a knowledge gap between the solid state stability and dissolution performance?

Topic 2: Selecting the Right Excipients and Understanding Their Impact on Oral Drug Bioavailability

Moderator: Ajit S. Narang, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co. - Biography

- How does drug self-association/micellization impact oral drug absorption and its modeling?
- When does drug excipient binding impact oral drug absorption? How can these be assessed experimentally?
- What could be the mechanistic reasons for variability in oral drug absorption, and how could these be investigated experimentally? What value do these studies add to the drug development process and decisions?

Topic 3: The Utility of Preclinical Animal Models in Predicting Human Absorption

Moderator: Ayman El-Kattan, Ph.D., Associate Research Fellow, Pharmacokinetic Dynamics & Metabolism, Pfizer, Inc. - Biography

- Overview of species differences in physiological/anatomical impact on oral absorption/first pass
- Assessment of the species differences in transporters/metabolizing enzymes impact on oral absorption
- Recommendation on approach to project human absorption

Topic 4: Microfluidics as Emerging Technology in Development of Poorly Soluble Drugs

Moderator: Sabiruddin Mirza, Ph.D., Sr. Research Associate, School of Engineering & Applied Science, Harvard University- Biography

- What are the advantages of microfluidics based technologies over the more traditional ones?
- Application and advantages of microfluidics in early stage development
- Where is this field progressing and what are the other examples of application of microfluidics technologies in drug delivery?

"Nice and informative meeting with high level presentations"

- Scientist, BIND Therapeutics

2nd Annual

Formulation and Drug Delivery

Strategies for Enhancing Solubility, Bioavailability and Faster Product Design and Development

FORMULATION & PROCESS DEVELOPMENT STRATEGIES

8:35 Chairperson's Opening Remarks
Ajit S. Narang, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co.

8:45 Formulation and Process Strategies for Preventing Form Conversion in Wet Granulation
Ajit S. Narang, Ph.D., Senior Research Investigator, Drug Product Science & Technology, Bristol-Myers Squibb Co.
Form conversions that are associated with hydration state change may be difficult to control during drug product processing and storage. In this presentation, a case study discussing the thermodynamic driver for form conversion would be presented. In addition, formulation and process strategies, such as the use of a hydrophilic polymer and control of processing conditions, to mitigate form conversion during processing would be discussed with a case study.

9:15 Optimizing Granulating Fluid Levels in High Shear Wet Granulation Using Wet Mass Rheology
Rahul R. Gandhi, Ph.D., Principal Scientist, Process Engineering Formulations, Dr. Reddys Laboratories Ltd.
This work demonstrates the use of wet mass rheology to optimize granulating fluid level (GFL) during high shear wet granulation (HSWG) of a formulation containing 90% API. Rheology is correlated with compactibility of final blends and dissolution rates of the tablet. This work is important to formulations with high API content that demonstrate lot-to-lot variability in material attributes. The use of wet mass rheology to optimize granulating fluid levels for processability and product performance is demonstrated.

9:45 SELECTED POSTER PRESENTATION: Coupling Chemical Images of Dry Powder Inhalation Formulation Structure to Formulation Performance
Andreea Iuras, Doctoral Researcher, Laboratory of Biophysics and Surface Analysis, The School of Pharmacy, University of Nottingham
APIs intended for pulmonary delivery tend to agglomerate prior to release, leading to poor dispersion and low delivered doses to the lung. Dry powder inhaler formulations (DPIFs) containing the API and a lactose carrier improve the API performance by alleviating these problems. However, the de-aggregation behavior of DPIFs is poorly understood, leading to inconsistent therapeutic outcomes. This work investigates the correlation between formulation structure and formulation performance with the goal of classifying APIs based upon their distribution on the lactose carrier surface.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 FEATURED PRESENTATION: Solithromycin, a Fourth Generation Macrolide, the First Fluoroketolide in Development for Use in Oral and Intravenous Dosing Formulations for Adult and Pediatric Use
Prabhavathi Fernandes, Ph.D., President and CEO, Cempra, Inc.
In the last two decades there has been a focus on developing i.v. antibiotics. Hospitalization is expensive and exposes patients to hospital acquired infections. In many cases, a potent oral antibiotic can allow a patient to be treated as an outpatient. Solithromycin is in Phase 3 clinical development in oral and i.v. dosing formulations. If approved, solithromycin would be the first antibiotic in a generation to be available in oral capsule and suspension and as i.v. formulation to be able to treat all age groups, including young children.

11:15 Optimizing Physical Properties by Forming Co-Crystals for Pharmaceutical Development
Dedong Wu, Ph.D., Senior Scientist, Pharmaceutical Development, AstraZeneca
The presentation will introduce pharmaceutical cocrystal approach and discuss opportunities and challenges of cocrystal applications in drug development. Cases studies from on-going projects will demonstrate how to use cocrystals to optimize important physical properties of drug candidates, including solubility, physical stability and solid-state property (e.g. melting point), thus enhancing drug developability in terms of quality, cost and time.

11:45 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Lunch on Your Own

FORMULATION/PROCESS CHEMISTRY SHARED PRESENTATION

12:50 pm Chairperson's Opening Remarks

1:00 Bridging Drug Substance and Drug Product Development: The Role of Solid State Chemistry in an API Process R&D Organization
Shuang Chen, Ph.D., Senior Scientist, Process R&D, AbbVie, Inc.
This presentation provides an overview on the important role solid state chemistry plays throughout the development of drug candidates. Case studies are presented to highlight some of the benefits of having a dedicated solid state chemistry group within an API organization that effectively bridges between API and DP developments resulting in robust processes, manufacturing efficiencies, and improved timelines.

1:30 Close of Conference

Suggested Event Package:

May 20
Pre-Conference Short Course*
Nanotechnology for Enhancing Bioavailability of Poorly Soluble Drugs (Click here for details)

May 21-22
Formulation and Drug Delivery Conference

May 22
Recommended Dinner Short Course* (Dinner will be served)
Current Trends in Crystallization and Polymorphism: Experiment and Prediction (Part of Property-Based Drug Design Conference)

May 22-23
Efficient Process Chemistry Conference*
Property-Based Drug Design Conference* (Click here for details)

**Separate registration required*

7th Annual

Efficient Process Chemistry

Successes and Challenges in API Development

THURSDAY, MAY 22

11:00 am Registration

FORMULATIONS/PROCESS CHEMISTRY SHARED PRESENTATION

11:15 Optimizing Physical Properties by Forming Co-Crystals for Pharmaceutical Development

Dedong Wu, Ph.D., Senior Scientist, Pharmaceutical Development, AstraZeneca

The presentation will introduce pharmaceutical cocrystal approach and discuss opportunities and challenges of cocrystal applications in drug development. Cases studies from on-going projects will demonstrate how to use cocrystals to optimize important physical properties of drug candidates, including solubility, physical stability and solid-state property (e.g. melting point), thus enhancing drug developability in terms of quality, cost and time.

11:45 Enjoy Lunch on Your Own

MULTI-DISCIPLINE PROCESS R&D

12:50 pm Chairperson's Opening Remarks

Neelakandha S. Mani, Ph.D., Scientific Director, & Fellow, Discovery Sciences, J&J PRD

1:00 Bridging Drug Substance and Drug Product Development: the Role of Solid State Chemistry in an API Process R&D Organization

Shuang Chen, Ph.D., Senior Scientist, Process R&D, AbbVie, Inc.

This presentation provides an overview on the important role solid state chemistry plays throughout the development of drug candidates. Case studies are presented to highlight some of the benefits of having a dedicated solid state chemistry group within an API organization that effectively bridges between API and DP developments resulting in robust processes, manufacturing efficiencies, and improved timelines.

1:30 Investigative and Engineering Approaches in Chemical Process Development

Apurva Chaudhary, Ph.D., Principal Fellow, Project Leader, Chemical Development, Novartis US

Enhanced process understanding based on scale-up experiences and engineering approaches have been used to understand the mechanisms of reactions and then develop new large scale processes by minimizing by-products and enhancing yields.

2:00 Incorporating Continuous Flow Technology in Exploratory Process Development

Bryan Li, Ph.D., Associate Research Fellow, Chemical R&D, Pfizer Pharmaceutical Science

Continuous flow technology offers many advantages over batch methods, including precise control of stoichiometry, reaction time and temperature, high reproducibility, and often better reaction profile. While flow chemistry has been used widely in the fine chemicals arena, it has not been widely adopted in the pharmaceutical industry, especially in the early development stage. This presentation will discuss efforts and examples how flow technology is implemented in Pfizer's exploratory development portfolio.

2:30 Managing and Controlling the Life Cycle of Impurities in Drug Development

Sponsored by ACD/Labs

Ryan Sasaki, Director, Global Strategy, ACD/Labs

Based on scale-up priorities (cost-effectiveness, safety, practicality, etc.), the synthetic route of a drug will be altered, changed, and optimized throughout the drug development cycle. Managing the life cycle of this process, the fate of relevant impurities, along with all the associated data is a major challenge. This presentation will highlight a novel approach for Impurity Resolution Management to help better manage process knowledge.

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

THINKING AHEAD IN ROUTE DEVELOPMENT

3:45 Organo-Catalysis for Industrial Set Up: Development of a Green, Cost-Efficient Process for the Manufacture of (S)-Pregabalin

Mauro Adamo, Ph.D., Professor of Organic and Medicinal Chemistry, Centre for Synthesis of Chemical Biology (CSCB), Royal College of Surgeons in Ireland

This talk deals with the development of a new process for the manufacture of (S)-Pregabalin. The presentation will highlight the crucial elements of synthetic planning adopted and will provide an example of process development in terms of cost efficiency and E factor. We show that it is possible to redesign the synthesis of a large volume API using only cheap, readily available and recyclable catalysts that can be prepared from natural sources.

4:15 Practical Asymmetric Syntheses of Challenging Drug Candidates

Joerg Deerberg, Ph.D., Senior Research Investigator, Chemical Development, Bristol-Myers Squibb Co.

The manufacture of Active Pharmaceutical Ingredients (APIs) of increasing structural complexity, particularly those possessing multiple centers of asymmetry, requires practical chemical tools capable of sustaining the rigors of efficiency, robustness, and isomeric purity control. This presentation will summarize recent efforts at Bristol-Myers Squibb on a series of challenging drug molecules, each of which incorporates the above design principles, resulting in concise bulk syntheses with a high degree of efficiency and stereo control.

4:45 Exploring and Optimizing Cost-Effective Route toward DPP-IV Inhibitor Compounds

Nhut Diep, Ph.D., Principal Scientist, Chemical Development, Forest Laboratories

This presentation describes the efforts around optimization methods for preparing DPP-IV inhibitor compounds. We will illustrate the extensive exploration synthetic strategies that were developed for cost-effective, novel streamline process, temporary protection-deprotection sequence, and scalable process toward Dutogliptin. Efforts to identify a scalable process led to the discovery of several useful transformations, including the asymmetric lithiation-boronation of the Boc-pyrrolidine that provided a single compound; the development of a streamline-telescope coupling reaction and workup which led to a robust crystallization/purification method.

5:15 PANEL DISCUSSION

Moderator: Neal Anderson, Ph.D., President, Anderson Process Solutions

Panelists: Mahavir Prashad, Ph.D., Head, Chemical Dev. Unit US, Novartis; Roger Bakale, Ph.D., Sr. Director, Worldwide Chemical Process R&D, Teva Pharmaceuticals & others

6:15 Close of Day

> "A focused group with a diversified background. The interaction among the attendees was superb."
>
> Senior Principal Scientist, Chemical R&D, Pfizer

7th Annual

Efficient Process Chemistry

Successes and Challenges in API Development

FRIDAY, MAY 23

7:30 am Interactive Breakout Discussion Groups with Continental Breakfast

PROCESS DEVELOPMENT AND SCALE-UP CONSIDERATIONS

8:35 Chairperson's Opening Remarks

Neal Anderson, Ph.D., President, Anderson Process Solutions

8:45 FEATURED PRESENTATION: Telaprevir Route Development Retrospective

Gerald Joseph Tanoury, Ph.D., Senior Scientific Fellow, Process Chemistry, Vertex Pharmaceuticals

Telaprevir is a protease inhibitor approved for the treatment of Hepatitis C. This talk will highlight the efforts toward developing a cost-effective process for the manufacture of Telaprevir, with a focus on the chemical processes for two chiral intermediates which were cost drivers for the manufacture of drug substance.

9:15 Step Economy Considerations in Route Development and Scale-Up of Drug Candidates

Neelakandha Mani, Ph.D., Scientific Director and Fellow, Discovery Sciences, Janssen Pharma R&D

The number of steps used to synthesize a drug molecule represents the single most significant component that impacts the manufacturing cost of an API. Step economy is equally important in early development, where, while the cost of API is not critical, the speed of synthesis plays perhaps the biggest role in fast tracking early clinical development. Examples of strategies for step economy in the scale-up synthesis of multiple candidate molecules will be presented.

9:45 Development of Efficient Asymmetric Propargylations and Application on Pilot Plant Scale

Daniel Fandrick, Ph.D., Principal Scientist, Chemical Development, Boehringer Ingelheim

The development of general and operationally simple stereoselective propargylations utilizing a metallo-boron exchange with a propargyl boronate is presented. Application of our methodology provided a sustainable process towards the potent azaindole glucocorticoid agonist BI 653048 on a pilot plant scale. Development of a continuous flow process to prepare the key propargyl boronate reagent on 0.8 metric ton scale is also presented.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Belviq (lorcaserin): From Process Chemistry to Commercial Manufacture

Antonio Garrido Montalban, Ph.D., Senior Director, Chemical R&D, Arena Pharmaceuticals, Inc.

11:30 Examples of a Holistic Approach to Developing Efficient Processes and Scale-Up Strategies

Roger Bakale, Ph.D., Senior Director, Worldwide Chemical Process R&D, Teva

The process examples presented will highlight principles for maximizing efficiency and critical elements in selecting an optimal manufacturing process. Process selection criteria will include step and atom economy, minimization of unit operations and capital requirements, process operability and robustness as well as environmental, sustainability, and safety factors along with an evaluation and comparison of quality, supply chain, and intellectual property attributes. Cost modeling and cost sensitivity metrics are important research tools for comparing design strategies and finalizing process selection.

12:00 pm Targeting Epigenetics Using Human Cell Model Systems and Novel *In Vitro* Assays

Sponsored by DiscoveRx

Scott Pattison, Ph.D., Director, Business Development, BioSeek

DiscoveRx's *in vitro* assays and human model systems enable inhibitor characterization based on target profiles and effects on complex biological systems. Bromodomain inhibitor potency and selectivity was evaluated using BROMOscan™ quantitative binding assays and intracellular target engagement assays. Inhibitors were classified based on their phenotypic impact on primary human cell systems using BioMAP®. These assays can guide compound prioritization, indication selection and highlight potential safety issues to improve clinical success.

12:30 Session Break

MORE PROCESS CHEMISTRY CASE STUDIES

12:55 Chairperson's Opening Remarks

Mahavir Prashad, Ph.D., Head, Chemical Development Unit US, Novartis Pharmaceuticals Corporation

1:00 Process Research and Kilogram Synthesis of TAK-733, an Investigational, Potent MEK Inhibitor

Yuxin (Marilyn) Zhao, Ph.D., Senior Scientist, Process Chemistry Group, Takeda California, Inc.

TAK-733 is a MEK kinase inhibitor that bears a 6-fluoropyridopyrimidone core. A novel and scalable synthesis of TAK-733 was developed after systematic route scouting. It featured the construction of a fully substituted fluoropyridone from - -fluoromalonate and malononitrile through a one-pot, three-step cascade reaction. Other key steps included efficient formation of bicyclic pyridopyrimidone core and unexpected challenging nucleophilic displacement of chloride with fluoroiodoaniline. Subsequent thorough process development enabled 20 kilogram GMP production of TAK-733.

1:30 Incorporating Flow Chemistry

Timothy Braden, Process Chemistry Group, Chemical Product R&D, Eli Lilly and Company

2:30 Process Development of the Pyridyltriazine Candidate AMG 511

Neil Langille, Ph.D., Senior Scientist, Process R&D, Amgen

A synthetic route for the large-scale manufacture of a pyridyltriazine-containing drug candidate AMG 511 is presented. Initial research focused on providing efficient access to large quantities of an enantiomerically enriched pyridine-containing boronic acid intermediate and reliable synthesis of a protected aminotriazine fragment. With building blocks in hand, the team used a combination of transition-metal mediated coupling and aromatic substitution reactions to produce the target in a convergent fashion, while avoiding competing side-reactions and product degradation. The final product AMG 511 was ultimately produced as a maleic acid crystal form with favorable physical properties for further evaluation.

3:00 Close of Conference

Suggested Event Package:

May 21-22

Formulation & Drug Delivery Conference

May 22-23

Efficient Process Chemistry Conference

** Separate registration required.*

Sponsor & Exhibit Opportunities

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers..

Podium Presentations— *Available within Main Agenda!*

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by CHI, and more.

Breakfast & Luncheon Podium Presentations

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

Invitation-Only VIP Dinner/Hospitality Suite

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives (i.e. purely social, focus group, reception style, plated dinner with specific conversation focus).

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

2014 Exhibitors & Sponsors (As of January 27, 2014)

ACD/Labs
AntiCancer Inc.
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The Jackson Laboratory
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Taconic
VisualSonics
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Additional branding and sponsorship opportunities available!

For sponsorship and exhibit information, please contact:

Joseph Vacca
Business Development Manager
781-972-5431 | jvacca@healthtech.com

Looking for additional ways to drive leads to your sales team? One move can make all the difference!

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Web Symposia
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Advertising opportunities such as marketing and promotional emails are also available.

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#CHIWPC14

CHI's INTRONET Networking at its Best

The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people that you want to meet. This online system was designed with your privacy in mind and is only available to registered session attendees of this event.

World Pharma Congress Student Fellowship

Full time graduate students and PhD Candidates are encouraged to apply for the World Pharma Congress Student Fellowship. Applications are due by *March 7, 2014*.

- Interested students must complete the application for the 2014 Student Fellowship
- Fellows are required to present a scientific poster. A poster title and abstract are due at the time of the application
- All applications will be reviewed by the scientific review committee and the accepted students will be notified no later than March 14, 2014 if they were accepted for the 2014 Student Fellowship
- Accepted 2014 Student Fellows will receive a discounted conference rate of $195*, which must be paid in full by April 4, 2014
- This fellowship is limited to 10 students and is for the Main Conference Only*
- All accepted 2014 Student Fellows will be asked to help promote the conference onsite at their college, and throughout their social media networks
- Students not accepted for the 2014 Student Fellowship, can register at a discounted rate $295*, and will not be required to present a poster

** This discounted rate cannot be combined with any other discounts for this event. Your discounted rate does not grant access to any of the short courses or pre-conference events. It also does not include hotel, travel or meals*

PRESENT A POSTER AND **SAVE $50!**

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by April 4, 2014.

Register online, or by phone, fax or mail. Please indicate that you would like to present a poster. Once your registration has been fully processed, we will send an email with a unique link and instructions for submitting your abstract using our online abstract submission tool. Please see below for more information.

Reasons you should present your research poster at this conference:

- Your poster will be exposed to our international delegation
- Receive $50 off your registration
- Your poster abstract will be published in our conference materials
- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

Hotel & Travel Information

Conference Venue and Host Hotel:

Westin Boston Waterfront
425 Summer St.
Boston, MA 02210
T: 617-532-4600

Room Rate: **$269 s/d**
Reservation Cutoff: **April 23, 2014**

Please visit our conference website to book your reservations online or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate- availability basis. Rooms are limited, so please book early.

TOP REASONS TO STAY AT THE WESTIN BOSTON WATERFRONT HOTEL

Take advantage of the discounted group rate!

- Just three miles from Boston's Logan International Airport
- Complimentary wireless internet access in guest rooms
- A short walk, bus, taxi or train ride to Boston's historic sites and family attractions
- Minutes from some of Boston's finest restaurants
- Pet friendly

We understand that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block at the conference hotel allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

2nd Annual
Formulation and Drug Delivery

7th Annual
Efficient Process Chemistry

13th Annual
WPC World Pharma Congress

May 21-23, 2014
Westin Boston Waterfront, Boston, MA

Pricing and Registration Information

BEST VALUE! EVENT PRICING

Includes access to 2 conferences, excludes short courses	Commercial	Academic, Government, Hospital-affiliated
Advance Registration Rate until May 16, 2014	$2,799	$1,249
Registrations After May 16, 2014 and on-site	$2,899	$1,299

SINGLE CONFERENCE PRICING

Includes access to 1 conference, excludes short courses

Advance Registration Rate until May 16, 2014	$1,799	$749
Registrations After May 16, 2014 and on-site	$1,899	$799

Program Selection: When registering please indicate the one conference you will attend:

May 21-22, 2014	May 22-23, 2014
T1 Tumor Models for Targeted Therapy	T6 Tumor Models for Cancer Immunotherapy
T2 Imaging in Oncology	T7 *In vitro* Tumor Models
T3 Preclinical Drug Safety	T8 Epigenetics Screening
T4 Formulation & Drug Delivery	T9 Efficient Process Chemistry
T5 Targeting Pain	

SHORT COURSE PRICING

Single Short Course	$699	$399
Two Short Courses	$999	$699
Three Short Courses	$1,199	$899

May 20, 2014	May 22, 2014 *(Dinner will be served)*
SC1 Animal Models of Pain: Progress and Challenges	SC6 Refining API Process Development for Efficiency (Dinner)
SC2 Introduction to Drug Metabolism and Its Role in Drug Toxicity	SC7 How To Best Utilize Organotypic 3D Cell Cultures Assays in Oncology (Dinner)
SC3 Nanotechnology for Enhancing Bioavailability of Poorly Soluble Drugs	SC8 Computational Modeling of Cancer Genomics (Dinner)
SC4 Metastatic Tumor Models: Technology and Applications (Dinner)	
SC5 Safety Testing for Biological Drugs and Vaccines (Dinner)	

CONFERENCE DISCOUNTS

Alumni Discount	20% Off
Drug Safety Executive Council (DSEC) Members	25% Off
Poster Discount	$50 Off

POSTER DISCOUNT ($50 Off) Poster abstracts are due by April 4, 2014 Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact **jring@healthtech.com**.
* CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

ALUMNI DISCOUNT: Cambridge Healthtech Institute (CHI) appreciates your past participation at World Pharma Congress. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate. Please note: Our records must indicate you were an attendee of World Pharma Congress in the past in order to qualify.

Group Discounts are Available!
Special rates are available for multiple attendees from the same organization. For more information on group discounts contact David Cunningham at 781-972-5472

*Alumni, DSEC Membership, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.

If you are unable to attend but would like to purchase the World Pharma Congress 2014 CD for $750 (plus shipping), please visit WorldPharmaCongress.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/ Cancellations Policy, go to http://www.healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

How to Register: **WorldPharmaCongress.com**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **FRM F** when registering!