

5TH ANNUAL CONTROLLED & MODIFIED DRUG RELEASE

"A must-attend for any drug manufacturer looking to innovate their product portfolio"
 - Senior Scientist, Merck & Co.

SUMMIT

NOVEMBER 28-29, 2018 | MARRIOTT PHILADELPHIA DOWNTOWN HOTEL | PHILADELPHIA, PA

Learn over 2 YEARS worth of new product development strategies, formulation approaches, delivery technologies and regulatory updates while decreasing drug product time-to-market in just 2 days!

Distinguished Speaker Faculty Includes:



Steve Byrn, PhD
 Charles B. Jordan
 Professor of Medicinal
 Chemistry
 Purdue University



Viral Kansara, PhD
 Vice President
 of Discovery
 Clearside Biomedical



Luis Santos, PhD
 Scientist II, Dosage
 Form Design & Develop-
 ment (DFDD)
 MedImmune



Dhaval Patel, PhD
 Senior Research Investigator
 I-Research Investigator
 Bristol Myers Squibb



Amit Joshi, PhD
 Senior Manager,
 Advanced Sourcing &
 Innovation
 Johnson & Johnson



Gaurav Tolia, PhD
 Senior Lead Scientist
 Mylan



Pavel Farkas, PhD
 Senior Director
 Biopharmaceutics/
 Clinical Development
 Teva



Mike de Leeuw, PhD
 Founder & Chief
 Executive Officer
 OncoLize



Lilly Roy, PhD
 Scientist II
 Vertex
 Pharmaceuticals



Grace Okoh, PhD
 Associate Principal
 Scientist
 Merck & Co.

Speakers Include:

- Amgen
- AstraZeneca
- Bioduro
- Biogen
- Celgene
- Clearside Biomedical
- Bristol-Myers Squibb
- Genentech
- GlaxoSmithKline
- Johnson & Johnson
- Insmad
- MedImmune
- Merck & Co.
- NIH
- Novartis
- OncoLize
- Pfizer
- Princeton University
- Purdue University
- Shire Pharmaceuticals
- Teva
- Vertex Pharma
- And many more...

Why Attend?

- **45+** industry-led speaker faculty over 2 full days sharing innovative drug development take-home strategies
- **12+** hours of networking sessions and breaks over two full days to learn from network with pharmaceutical and biotech senior formulation, development and delivery professionals
- Pre-conference workshop on **Oral Controlled Release Solid Dosage forms**
- **160+** Senior Participants spanning pharma, biotech and specialty delivery & technology companies
- **Dynamic Tech Showcase Hall** with multiple leading manufacturing, formulation development, delivery and modeling experts
- **2 Events** for the Price of 1!
 Co-located and shared exhibition with the 3rd Peptide Drug Design & Delivery Summit



Join our "Novel Drug Discovery & Development" LinkedIn Group

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In today's high-risk, overcrowded and highly regulated drug development marketplace, we understand the drug development industry is in critical need of innovative delivery and formulation approaches in order to get new approved drug products to market in a timely fashion. Based on the successes of the previous events, the **5th Annual Controlled and Modified Drug Release Summit** is taking place in Philadelphia, PA on November 28-29, 2018. This **MUST-ATTEND** intensive 2-Day program will share innovative controlled and modified drug release strategies that will benefit your current and future product pipelines.

Learn directly from industry's leading experts and hear unique case study sessions and take-home examples to enhance your product pipeline. Gather insights into the latest technologies and methods in improving drug release mechanisms, maximizing exposure, and reducing time-to-market. Additionally, this must-attend event will showcase the latest regulatory guidance updates and the implications for the industry.

By attending this conference, you will hear 20+ sessions and case studies including:

- Localized & targeted delivery
 - Pediatric dosage forms & delivery
 - QBD Strategy
 - Novel alliance management strategies
 - Regulatory guidance for modified release dosage forms
 - Enhancing patient adherence for drug delivery
 - Evaluating innovations in oral drug formulation and delivery technologies
 - Implementing innovative strategies around drug / device combinations
 - Advances in ocular delivery
 - Parenteral routes of administration
 - Topical and Transdermal Delivery
 - Combining In-Vivo animal models with physiologically-based PBPK modeling
 - Enhancing macromolecule delivery
 - Modified release technologies for product lifecycle extensions
- And many more...*

Previous attendees spanned **15+ countries** including representation from North America, Central America, South America, Asia and Europe. No other event addresses the major drug development opportunities that will result by bridging the scientific and regulatory disconnect which currently hampers the industry.

Benefit from industry participation from **Pfizer, Merck, Novartis, Bristol Myers Squibb, GlaxoSmithKline, Celgene, Johnson & Johnson**, and many more controlled and modified drug release innovators.

Engage in dynamic conversation with your industry peers at our multiple networking sessions, and takeaway novel controlled and modified release strategies, which could speed up time to market and save your organization millions. We hope you will join us in Philadelphia this November to enhance your drug delivery and formulation capabilities and increase time to market on drug products.

Sincerely,

Simon Curtis
CEO & Co-Founder
Curtis & Coulter LLC

P.S. Do not miss the pre-conference workshop on Oral Controlled Release Solid Dosage forms!

Philadelphia Marriott Downtown

Philadelphia Marriott Downtown welcomes you with spacious style, exceptional service and an incredible Center City location. Whether you're joining us for business or on vacation, you'll be thrilled with our hotel's well-designed rooms and suites, which offer deluxe bedding and thoughtful amenities. Elsewhere at the hotel, you can enjoy a workout in the fitness center, followed by a swim in the heated indoor pool.

Our unrivaled downtown location keeps guests in the thick of things, and we are minutes away from transportation hubs such as Philadelphia International Airport (PHL) and Amtrak's 30th Street Station, as well as the Pennsylvania Convention Center.

Discounted Room Rates Available through Curtis & Coulter

To book overnight accommodations at the Philadelphia Marriott Downtown Hotel with Curtis & Coulter's discounted room rate, please quote "Curtis & Coulter's November Meeting". Please book your room early or **BEFORE NOVEMBER 6th, 2018**, as the rooms available at this rate are limited.

Venue Information

Philadelphia Marriott Downtown

1201 Market St,
Philadelphia, PA 19107
Phone: (215) 625-2900

Who Should Attend?

Pharmaceutical, biotech and academic professionals specializing in:

- Drug Delivery
- Pharmaceuticals
- PK-PD
- Physicochemistry
- Formulation/Pre-Formulation
- Medicinal/Analytical / Solid state Chemistry
- Preclinical/Analytical Development
- Product Enhancement/Development
- CMC
- Regulatory Affairs
- Drug Discovery
- Life-Cycle/Portfolio Management
- Partnering, Licensing & Alliance Management
- Intellectual Property
- Toxicology
- Process R&D

This Program Will Also Be of Interest to:

- Specialty Delivery and Formulation Service Providers
- API Manufacturers
- CROs
- CMOs

Sponsorship & Exhibiting Opportunities

The 5th Controlled & Modified Drug Release Summit is the perfect platform to engage pharma and biotech companies over 2 valuable interactive days. Sponsoring at the Summit allows you to announce your new products and services, generate new leads, extend brand awareness and maintain existing relationships.

Limited packages currently available include:

30 Min Speaking Engagements – Panel Participation – Networking Drinks Reception Chairing – Branding Sponsorships – Exhibiting Only

Interested in finding out more? Schedule a call TODAY!

Click [HERE](#) to set an appointment

(Please note that sponsorship opportunities are limited due to the educational-led focus of this event. Please enquire for availability.)*

Pre-Conference Workshop Day – Tuesday, November 27th, 2018

2:45PM – 3:00PM Registration for Workshop Attendees

3:00PM – 5:00PM **Pre-Conference Workshop: Oral Controlled Release Solid Dosage forms**

During this intensive workshop, presentations from industry will cover the entire spectrum, ranging from engineering aspects during the manufacturing process, the portfolio of commercially available excipients allowing to formulate a large variety of drugs, the underlying

mass transport mechanisms and physical principles, characterization methods for the key properties of the devices as well as potential pitfalls and hurdles to be overcome during product development will be addressed.

Day One – Wednesday, November 28th, 2018


7:30 Registration Opens & Continental Breakfast for Attendees

8:30 **Collaboration is King! Ice Breaker**


For today's drug manufacturer, the idea of collaboration is one that should never leave the table. Successful organizations will ensure that their internal departments are working hand-in-hand with one another. And, even more successful companies know that there could be huge benefits to reap by collaborating with others across the healthcare ecosystem. To instill this idea of collaborating for success, we are going to play a fun little ice-breaker game.

8:45 Chairperson's Day One Welcome and Opening Remarks


8:50 **KEYNOTE SESSION: Breakthrough Innovations in the Next Generation of Controlled Delivery Systems**

 **Robert Langer, PhD**
David H. Koch Institute Professor,
MIT (Invited)

9:20 **REGULATORY UPDATE: Global Guidance on Pharmacokinetics and Clinical Evaluation of Modified Release Dosage Forms**


 **Pavel Farkas, PhD**
Senior Director Biopharmaceutics/Clinical
Development
Teva

10:00 **Decreasing Time-to-Market via Synchrotron Utilization to Discover Stable Formulation**

 **Steve Byrn, PhD**
Charles B. Jordan Professor of Medicinal Chemistry
Purdue University

10:40 Morning Networking & Refreshment Break in Exhibit Hall

11:10 **Alternative Therapeutic Fields for Inhalation Drug Development**


 **David Cipolla, PhD**
Vice President, Research
Insmed Incorporated


11:50 **PANEL SESSION: Exploring Innovative Collaborations to Support The Next Generation of Drug Products**


Participants:

 **Laszlo Otvos, PhD**
Adjunct Professor
Semmelweis Medical School

 **Amit Joshi, PhD**
Senior Manager, Advanced Sourcing & Innovation
Johnson & Johnson

 **Dana Ault-Riche, PhD**
Chief Executive Officer
Reflexion Pharmaceuticals


 **Mike de Leeuw, PhD**
Founder & CEO
Reflexion Pharmaceuticals

 **Marian Gindy, PhD**
Director, Parenteral Products Development
Merck & Co. (*Subject to final confirmation)


12:30 Networking Lunch in the Exhibit Hall

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1:30 **Evolution of Nanoparticle Delivery: Targeted Approaches in Oncology Drug Development**

 **Piotr Grodzinski, PhD**
Director, NCI Office of Cancer Nanotechnology Research
NCI / NIH

2:05 **Comparing Pharmacokinetic Performance of an Osmotic Tablet against a Matrix Tablet in Beagle dogs: Case Study of a BCS class II Molecule**


 **Mikolaj Milewski, PhD**
Principal Scientist, Oral Biopharmaceutics/Drug Absorption
Merck & Co

2:40 **Nucleic Acid Delivery: Enabling the Next Generation of Therapeutics**


 **Luis Santos, PhD**
Scientist II, Dosage Form Design & Development (DFDD)
MedImmune

3:15 Afternoon Networking & Refreshment Break in Exhibit Hall

3:50 **Gene Editing in vivo with Cas9 RNP and Donor DNA Complexed to Gold Nanoparticles**


 **Niren Murthy, PhD**
Professor, Bioengineering
UC Berkeley

4:25 **Design and Evaluation of Sustained Ocular Delivery Systems**


 **Viral Kansara, PhD**
Vice President of Discovery
Clearside Biomedical

3RD PEPTIDE DRUG DESIGN & DELIVERY • SUMMIT •

1:30 **What's Next for Peptide Development? Effective Strategies for Customizing Existing Delivery Platforms for New Products**

 **Marian Gindy, PhD**
Director, Parenteral Products Development
Merck & Co. (*Subject to final confirmation)


2:05 **Next Generation Product Development: Developing and Commercializing D-Amino Acid Proteins and the Opportunities for Industry**

 **Dana Ault-Riche, PhD**
Chief Executive Officer
Reflexion Pharmaceuticals


2:40 **Targeted Peptide Delivery via Novel Routes of Administration Whilst Maintaining Stability**

 **Sandhya Girish, PhD**
Director/Senior Scientist, Global Head Oncology, Clinical
Pharmacology Development Sciences
Genentech

3:50 **Delivery and Controlled Release from Nanoparticles for Drug Delivery & Imaging**

 **Robert Prud'homme, PhD**
Professor, Department of Chemical & Biological Engineering
Princeton University

4:25 **Towards the Use of ADP355: First-in-Class Adiponectin Receptor Agonist Peptide in NASH**

 **Laszlo Otvos, PhD**
Adjunct Professor
Semmelweis Medical School

5:00 Solution Engine Screening for Rapid Identification of Controlled Release Matrices



Blair West, PhD
Chief Scientific Officer, Global CMC Solutions
BioDuro

5:00 Enabling Oral Delivery of Peptides with Novel Approaches to Mature Technology



Jason LePree, PhD
Senior Principal Scientist, Application Laboratory
Gattefossé USA

5:35 Chair's Closing Remarks, Drinks Reception and End of Day One

Day Two – Thursday, November 29th, 2018

8:00 Registration Opens & Continental Breakfast for Attendees

8:55 Chair's Closing Remarks, Drinks Reception and End of Day One

9:00 Oral Controlled Release - Novel Formulations, Technologies and Development Strategies



Dhaval Patel, PhD
Senior Research Investigator
Bristol Myers Squibb

9:00 Developing a New Class of Metabolically Stable Peptide-Like Therapeutics with Unique Molecular Biology Properties



Scott Shandler, PhD
Founder & Chief Executive Officer
Longevity Biotech

9:35 Oral Modified Release Drug Products: Applications and Considerations for Selection



Grace Okoh, PhD
Associate Principal Scientist
Merck & Co.

9:35 Paradigm Shift in Potential Treatment for Type 2 Diabetes with Once a Year or Half Yearly Dosing of GLP-1 Agonist



Ved Srivastava, PhD
Intarcia Therapeutics

10:10 An Erosion-Based Approach to Oral Drug Delivery



Carol Thompson, PhD
Chief Executive Officer
BDD Pharma

10:10 Using Peptides for Targeted-Cancer Therapy: A Novel Strategy for Improving Stability and Half-Life



Mamoun Alhamadsheh, PhD
Associate Professor of Pharmaceutical Chemistry
University of the Pacific

10:45 Morning Networking & Refreshment Break in Exhibit Hall

11:15 Nanotechnology Approaches for Localized and Targeted Treatment of Lung Diseases



Tamara Minko, PhD
Distinguished Professor and Chair
Rutgers University

11:15 Peptide Microarrays as a Drug Discovery Platform Technology



Chris Diehnelt, PhD
Assistant Research Professor,
Biodesign Center for Innovations in Medicine
Arizona State University

11:50 Utilizing Intrinsic Properties of Pressure Sensitive Adhesive for Transdermal and Oral Controlled Release



Gaurav Tolia, PhD
Senior Lead Scientist
Mylan

11:50 Localized Ocular Delivery of Peptides for Enhanced Exposure



Susan Crowell, PhD
Senior Scientist, PKPD
Genentech

12:25 Networking Lunch in the Exhibit Hall

1:30 Evaluating Disintegration Mechanisms that Improve Bioavailability from Immediate Release Tablets using FBRM



Lilly Roy, PhD
Scientist II
Vertex Pharmaceuticals

1:30 Utilizing in vivo JetPEI for dsRNA delivery of Peptides



Yogita Krishnamachari
Associate Principal Scientist, Peptide Product Development
Merck

2:05 Impact of Enabling Drug Delivery Approaches on PK Performances



Indrajit Ghosh, PhD
Associate Director, Global Pharmaceutical Development
Celgene

2:05 Uncovering New Successes in Advancing an Oral Peptide to Market



Dieter Willbold, PhD
Director of ICS-6 Structural Biochemistry
Germany Forschungszentrum Julich

2:40 Afternoon Networking & Refreshment Break in Exhibit Hall

3:00 Affordable Targeted Delivery of Tumor-Based Drug Products



Mike de Leeuw, PhD
Founder & CEO
OncoLize BV

3:00 Cell Penetrating Peptides in Molecular Imaging and Drug Delivery



Salleta Prabhu, PhD
Director, Preclinical and Translational PKPD
Genentech (a member of the Roche Group)

3:35 Multiparticulate Drug Delivery Systems (MDDS) for Oral Modified Release (MR)



Sree Nadkarni, PhD
Senior Director, Pharma Development
Biotie Therapies

3:35 Examining Commercial Advances in Peptide synthesis; Biosynthesis and Modified Peptides and Scale-Up

* Speaker to be confirmed shortly

4:10 Chair's Wrap-up & Conference Concludes

Create your own event with Curtis & Coulter!

We at Curtis & Coulter believe creativity and forward thinking ultimately drive innovation within the life science community. We understand this can be a challenging task, given the highly regulated nature of the industry. Our experience, skill, creative vision and commercial drive have enabled us to offer the life science community an unparalleled array of educational and networking opportunities.

We develop and tailor our unique events specifically for multiple-sized pharmaceutical, biotech, biopharmaceutical, medical device, academic and government organizations.

Whether you are looking to learn cutting-edge industry developments, expand your business or network with industry peers, Curtis & Coulter will be able to help you achieve your educational, marketing and commercial goals.

REGISTRATION OPTIONS



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Call +1 (646) 604 2821
and we'll register you over
the phone in 2 mins!



Register By Mail:
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New York, NY 11103
We'll confirm attendance
on receipt!



Register Online:
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Register via Email:
Fill out form on the next page
and email [registration@
curtiscoulter.com](mailto:registration@curtiscoulter.com) to register!

Registration Fees for Attending Curtis & Coulter's 5th Controlled & Modified Drug Release Summit:

EVENT PRICING

Registration Date	Conference Only	Conference & Pre-Conference Workshop
Register Before October 30, 2018	\$1895 (Save \$100)	\$2095 (Save \$100)
Regular (Register On or After October 30, 2018)	\$1995	\$2195
Register Onsite November 28, 2018	\$2095	\$2295

Group Registration Discount Programs

Save 25% per person when registering four

- For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register 4 at one time) this is a savings of 25% per person.

To find out more on how you can take advantage of these group discounts, please call **+1(646) 604-2821** or email registration@curtiscoulter.com

Registration Fee

The fee includes the conference, all (available) program materials, and designated continental breakfasts, lunches and refreshments.

Please make registration checks payable to **Curtis & Coulter, LLC** and **write code CR5 on the back of your check**. You may also use Visa, MasterCard, Discover or American Express via our [secure registration gateway](#) on Active Network. Payments must be received in full prior to the commencement of the conference. All discounts will be applied to the Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at the time of order. Group discounts are available when organizations register four or more employees simultaneously.

Cancellation & Replacement Policy

Any registration received is non-refundable. If you need to cancel your registration for any reason, a voucher to another event valid for 18 months from the voucher issue date will be issued. A replacement of similar level of seniority is permitted at no extra cost.

In the event Curtis & Coulter LLC cancels the event for any reason the contract may be re-assigned to a rescheduled date and the sponsor/exhibit fee applied. Curtis & Coulter LLC will not be responsible for any airfare, hotel or other costs incurred by sponsor/exhibitor and registrants due to event cancellation. In no event shall Curtis & Coulter LLC be liable for indirect or consequential damages.

Curtis & Coulter LLC assumes no liability whatsoever due to a fortuitous event, unforeseen occurrence or any other event that results in Curtis & Coulter LLC having to cancel, reschedule or postpone the event. A fortuitous event shall include, but not be limited to; an Act of God, flood, fire, war, terrorism, governmental restrictions, work strike, extreme weather conditions or any other emergency.

Curtis & Coulter LLC reserves the right to cancel any conference due to extenuating circumstances it deems necessary and will not be responsible for airfare, hotel or any other costs incurred by registrants.

Curtis & Coulter LLC reserves the right to make changes to the speaker faculty and agenda LLC without notice. In the event of a speaker cancellation, every effort to find a suitable replacement will be made.

The opinions of this faculty do not necessarily reflect those of the companies they represent or Curtis & Coulter LLC.

CURTIS & COULTER

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Vertex
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Grace Okoh, PhD
Associate Principal
Scientist
Merck & Co.

Promo Code

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Head of Formulation or Pharmaceutical Development

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Curtis & Coulter LLC
28-12 36th St, Suite 2R
New York, NY 11103

We'll confirm attendance on receipt!



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Email:

registration@curtiscoulter.com

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Registration

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EARLY-BIRD PRICING

Register before October 30, 2018 for Early-Bird pricing:

Conference ----- \$1,895 / \$2,095

Register on or after October 30, 2018 for Regular pricing:

Conference / with workshop ----- \$1,995 / \$2,195

ONSITE PRICING

November 28, 2018

Conference / with workshop ----- \$2,095 / \$2,295

PAYMENT

Please charge my VISA Mastercard AMEX Please invoice me

Number _____ Exp. Date _____

(for credit card authorization and opt-in marketing)

Signature _____

I have enclosed my check for \$ _____ made payable to Curtis & Coulter.