

Pre-conference Workshop CC-CRS/CSPS

**Date:** May 10, 2017

**Title:** Pharmaceutical Polymer Materials for Controlled Release Dosage Forms

**Organizing committee:** Shirley X.Y. Wu (Chair), Marta Cerruti, Marc Gauthier, Emmanuel Ho, Larry Unsworth, Yufei Chen, CC-CRS

**Co-Chairs:** Shirley X.Y. Wu, University of Toronto  
Marta Cerruti, McGill University  
Marc Gauthier, Énergie Matériaux Télécommunications Research Centre

**Sponsors:** BASF, Colorcon

**Location:** McGill University, Ballroom (3rd floor), Students Society of McGill University  
University Center, 3480 McTavish, Montreal, QC Canada

**Description:**

Polymeric materials have been used widely in pharmaceutical products, in particular in controlled release dosage forms. Fully understanding their properties will help rational design of controlled release dosage forms. This workshop will cover introduction to pharmaceutical polymers, fundamentals of controlled drug release, dosage form design, manufacturing of such dosage forms using pharmaceutical polymer materials. Experts from both academia and industry will present basic science and practical topics and discuss with participants in panel discussion section.

| Time          | Topic  | Speaker  | Moderator                                |
|---------------|--|--|--|
| 8:00 – 8:30   | Registration, continental breakfast and networking   |  |  |
| 8:30 – 9:25   | Introduction to pharmaceutical polymers and their roles in controlled release dosage forms | <i>Shirley X.Y. Wu</i><br>University of Toronto  | Todd Hoare                               |
| 9:25 – 10:25  | Starch derivatives as multifunctional excipients for drug delivery systems                 | <i>Mircea A. Mateescu</i><br><i>Pompilia Ispas-Szabo</i><br>University of Quebec at Montreal | Shirley Wu                               |
| 10:25 – 10:45 | Coffee break   |  |  |
| 10:45 – 11:45 | Polymers for solubility enhancement and solid dispersion dosage forms                      | <i>Shaukat Ali</i> , PhD<br>Technical Support Manager, BASF                                  | Shirley Wu, Todd Hoare                   |
| 11:45 – 1:00  | Lunch and networking   |  |  |
| 1:00 – 2:00   | Applications of cellulose ether barrier membrane coatings in oral solid dosage forms       | <i>Florent Vilotte</i> , Senior Area Technical Manager, Colorcon                             | Shirley Wu, Marta Cerruti, Marc Gauthier |
| 2:00 – 3:00   | Recent developments around formulation of hydrophilic controlled release matrices          | <i>Manish Rane</i> , Ph.D.<br>Product Development Manager – Innovation Colorcon              |  |
| 3:00 – 3:30   | Panel discussion   | All speakers with attendees  |  |
| 3:30 – 3:35   | Closing remarks  | <i>Marc Gauthier</i> , INRS  |  |

**Registration (free):** <http://cc-crs.com/CRS/?p=560>

For further information, please contact [ophelie.gourgas@mail.mcgill.ca](mailto:ophelie.gourgas@mail.mcgill.ca)

## WORKSHOP ORGANIZING COMMITTEE



Prof. Shirley X.Y.  
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Toronto



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McGill University



Prof. Marc  
Gauthier (Co-chair)  
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Prof. Emmanuel  
Ho  
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Prof. Larry  
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University of  
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Mr. Yufei Chen  
(PhD student)  
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## ACKNOWLEDGEMENTS

### WORKSHOP SPONSORS



## DIRECTOR BOARD OF CANADIAN CHAPTER OF CONTROLLED RELEASE SOCIETY (CC-CRS)

### STUDENT VOLUNTEERS

Ophelie Gourgas (McGill University)

Dhanalakshmi Jeyachandran (McGill University)

Fatemeh Zare (Institut National de la Recherche Scientifique, INRS)

Ahlem Zaghmi (Institut National de la Recherche Scientifique, INRS)

## PRESENTATION ABSTRACTS AND SPEAKERS' BIOGRAPHY

### Introduction to pharmaceutical polymers and their roles in controlled release dosage forms

Prof. Shirley X.Y. Wu

Advanced Pharmaceutics & Drug Delivery Laboratory  
Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto ON Canada

**Abstract:** Despite numerous polymers have been synthesized and studied for drug delivery applications for over six decades, only a small portion of polymers have been used in approved pharmaceutical products. These polymers are generally categorized as pharmaceutical excipients. Of various pharmaceutical polymers, a few groups are frequently employed to formulate controlled release dosage forms, also called modified release products.

This presentation will provide an overview of pharmaceutical polymers, their properties and roles in controlled release dosage forms. Controlled release mechanisms, structure of drug delivery systems, and their impact on drug release profiles of pharmaceutical products will be reviewed. Representative pharmaceutical polymer materials used in these products will be introduced alongside.

#### Speaker's Biography:



Dr. Xiao Yu (Shirley) Wu (PhD from McMaster University) is a full Professor in pharmaceutics & drug delivery, elected Fellow of American Association of Pharmaceutical Scientists. Since joined the University of Toronto in 1994, Dr. Wu has directed an innovative and productive research program and had extensive collaborations with scientists in academia and pharmaceutical industry. She has trained ~150 graduate and undergraduate research students, and postdoctoral researchers, published >150 journal papers and book chapters, 270 proceedings and abstracts, and is a co-inventor of 26 issued or pending patents. She received Astra Pharma-AFPC New Investigator Research Award (1999) and AFPC-Pfizer Research Career Award (2016). Her current research includes blood-brain barrier-crossing nanoparticles for brain cancer and CNS diseases, synergistic drug combination nanomedicine for multidrug resistant and metastatic breast cancer, hybrid bioreactive nanoparticles for remodeling tumor microenvironment to improve therapies, intelligent polymer and nanotechnology-enabled closed-loop insulin delivery, and mechanism-based and computer-aided design of controlled release drug delivery systems.

## Starch derivatives as multifunctional excipients for drug delivery systems

Profs. Mircea Alexandru Mateescu and Pompilia Ispas-Szabo

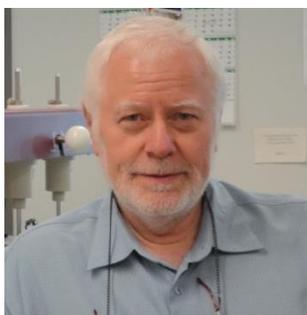
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**Abstract:** The presentation will target the usefulness of a large variety of starch derivatives as excipients for solid oral pharmaceutical dosage forms with a focus on drug delivery systems.

The synthesis, applications and aspects of structure – properties relationship will be discussed with the aim to evidenciate how starch-based excipients can function as multi-task materials and how changes at molecular level are translated in new functions. Differently from other polymers, starch integrates advantages of natural source, biocompatibility, gel-forming and film-forming material associated with enzymatic susceptibility. The easy-modification of its structure by physical or chemical procedures, allowed the preparation of a wide range of neutral or ionic derivatives to be used for high loaded dosage forms as matrices for delayed, controlled or chronodelivery of drugs. Starch derivatives complexation and semi-interpenetrated networks obtained in combination with other polyhydroxilic polymers will illustrate additional pharmaceutical applications and the high potential of starch derivatives as pharmaceutical excipients.



**Prof. Mircea Alexandru Mateescu**

Department of Chemistry, University du Québec à Montréal, Montreal (QC)  
Canada

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### Speaker's Biography:

M. A. Mateescu (PhD from Bucharest Polytechnic University and receiver of a “Honorary Laurea” from Rome University “La Sapienza”) is full Professor at UQAM since 1994. His research relates to Drug Targeting and to Multifunctional Proteins. Co-inventor of more than 30 patents covering new excipients for drug delivery and therapeutic enzymes, Dr Mateescu developed fruitful collaborations with pharmaceutical companies and was involved in several technological transfers. He published more than 130 papers in reputed journals, one book, 8 book-chapters. He is holder of Bombardier Prize (1999) for Technological Innovation in Canada, of Venezia Prize (Italian Chamber of Commerce, 2012), of Research-Career Prize (UQAM, 2014).



## **Pompilia Ispas-Szabo**

Department of Chemistry, University du Québec à Montréal, Montreal (QC)  
Canada

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### **Speaker's Biography:**

Dr. Pompilia Ispas-Szabo is adjunct professor at Université du Québec à Montreal (UQAM, Canada) and a Research & Development scientist in pharmaceutical industry. She completed her M.Sc in Physical Chemistry at Bucharest University and the Ph.D. at UQAM. Co-inventor of new excipients proposed as matrices for controlled drug delivery or new products, she worked in various Canadian pharmaceutical companies (Smaratrix Technologies, IntelGenx Corp., Aptalis Pharma, etc.), being involved in the development of innovative products or technological platforms. Co-author of 10 patents/applications, more than 50 papers and proceedings, one book, two book-chapters, she is recognized for her contribution to academic and industrial innovation.

## **Polymers for solubility enhancement and solid dispersion dosage forms**

**Shaukat Ali**, PhD, BASF Corporation, Florham Park, NJ 07932

**Abstract:** BASF offers a range of high functional polymeric excipients and solubilizers in development of solid and liquid oral dosage formulations under its core Solubilization platform. Many of these excipients have widely been used in solid dispersion technologies including hot melt extrusion, spray drying, Kinetisol<sup>®</sup> among others, for enhancing solubility and bioavailability of poorly soluble compounds.

This presentation will focus on two excipients, Kollidon<sup>®</sup> VA64 and Soluplus<sup>®</sup>, and their application in conventional and non-conventional technologies. The case studies involving the utilities of twin screw wet granulation and hot melt extrusion technologies will be presented to demonstrate the selection of two technologies for development of a model drug.

### **Speaker's Biography:**



Shaukat Ali has worked in the pharma industry for over 23 years including 13 years at BASF. His area of expertise includes the controlled release, lipid based emulsifying systems (SEDDS/SMEDDS), liposome drug delivery, and film development technology. He received his PhD in chemistry from the City University of New York, and postdoctoral training from the University of Minnesota and Cornell University. He serves as a member of the editorial advisory board of several pharmaceutical journals. He also serves as a panel of expert in the USP expert committees for General Chapters- Physical Analysis, Continuous Manufacturing and Excipient Performance <1059>. He has published 45 articles in the scientific journals and is the inventor in 14 US Patents.

## **Applications of cellulose ether barrier membrane coatings in oral solid dosage forms**

**Florent Vilotte**, Senior Area Technical Manager, Colorcon Canada

**Abstract:** Ethylcellulose, a cellulose ether polymer has been used in various solid oral formulations for modified release barrier membrane coating on tablets and multi-particulates. They are safe, well known and accepted by regulators around the world and provide robust formulation option. This presentation will cover the different ethylcellulose based coatings, such as Opadry EC<sup>®</sup> for organic coating and Surelease<sup>®</sup> for aqueous coating application on different solid oral dosage forms for extended release formulations or and taste masking of bitter drugs.

### **Speaker's Biography:**



Florent has more than 20 years of experience in various pharmaceutical dosage forms. He has worked in Europe and North America. He is with Colorcon for 15 years and is currently based in Montreal, Canada. Prior to joining, he worked for Manesty in the UK as Process technologist and Roche in France as Formulator and Scale-Up Technician. During his career, Florent has acquired significant practical pharmaceutical formulation and process development expertise. Florent holds a degree in Industrial Pharmaceutical Development and Dietetics.

## **Recent developments around formulation of hydrophilic controlled release matrices**

**Manish Rane**, PhD

Product Development Manager - Innovation at Colorcon US

**Abstract:** Hydrophilic controlled release matrices have been hugely popular, both amongst formulators, clinicians and patients. This presentation will give a quick overview of hydrophilic matrix tablet technology for extended release and focus on recent developments in this technology to improve patient compliance as well as high manufacturing productivity with prime objective to achieve necessary safety, efficacy and quality.

### **Speaker's Biography:**



Manish Rane has more than 17 years of experience in various pharmaceutical dosage forms. He has worked in Asia and North America. He is with Colorcon for more than 9 years and currently based in Harleysville, PA, USA. Prior to joining Colorcon, he worked with Nicholas Piramal India and Alkem Labs in India. Manish did his B. Pharm. Sci, M. Pharm. Sci. and Ph.D. in Pharmaceutical Technology from University of Mumbai. He has to his credit more than 25 publications, posters and book chapters, one patent and more than 200 presentations.