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5th International Summit on

# GMP, GCP & Quality Control

August 12-13, 2016
Toronto, Canada





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# Conference Day One | Friday August 12, 2016

## MacDolald

| | |
|---|---|
| 08:30-09:30 | Registrations |
| 09:30-09:55 | Opening Ceremony |

Session Chair: **Boyd L Summers,** BL Summers Consulting. LLC, USA

### Keynote Forum

| | |
|---|---|
| 10:00-10:30 | **Title:** Planning to outsource manufacturing: Have you done your homework?<br>**Mohammed R Khan,** Synergex Consulting, Canada |
| 10:30-11:00 | **Title:** Ensure quality assurance for companies and institutions<br>**Boyd L Summers,** BL Summers Consulting LLC., USA |

**Refreshments and Networking Break 11:00-11:20 @ Foyer**

| | |
|---|---|
| 11:20-11:50 | **Title:** Current FDA audit trends and most common cited drug GMP deficiencies<br>**Kenneth Christie,** VTS Consultants, Inc., USA |
| 11:50-12:20 | **Title:** Importance of characterization of variation in the secondary endpoint measures prior to the trial: a key to a successful outcome of phase 1 trial and progression to a phase<br>**Danuta Radzioch,** McGill University and Laurent Pharmaceuticals Inc., Canada |
| 12:20-12:50 | **Title:** Traceability guide for general food manufacturers<br>**Nadia Narine,** Lumar Food Safety Services Ltd., Canada |

**Lunch Break 12:50-13:30 @ Foyer**

| | |
|---|---|
| 13:30-14:00 | **Title:** Stability considerations from early stage development through phase-IV of pharmaceutical drug products<br>**Dharmi Trivedi,** Professional Pharmaceutical Quality and Compliance Specialist, USA |
| 14:00-14:30 | **Title:** Good clinical practices<br>**Peggy J Berry,** Synergy Consulting LLC, USA |

### B2B Meetings and Networking

# Conference Day Two | Saturday August 13, 2016

## MacDolald

Session Chair: **Reza Shojaei**, Canadian Plasma Resources, Canada

### Keynote Forum

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|---|---|
| 10:00-10:30 | **Ramakrishna Pidaparti**, Wipro Technologies, USA |
| 10:30-11:00 | **Title:** Quality risk management<br>**Rashid Mahmood**, Surge Laboratories Private Limited, Pakistan |

**Refreshments and Networking Break 11:00-11:20 @ Foyer**

| | |
|---|---|
| 11:20-11:50 | **Title**: GMP requirements for Canadian blood & blood establishments<br>**Reza Shojaei**, Canadian Plasma Resources, Canada |
| 11:50-12:20 | **Title**: Bioavailability and bioequivalence concerns in pharmaceutical industry<br>**Wael Ebied**, SEDICO Pharmaceutical, Egypt |
| 12:20-12:50 | **Title**: From molecules to market<br>**Luciano Calenti**, ACIC Fine Chemicals, Canada |

### B2B Meetings and Networking

**Poster Presentations**

| | |
|---|---|
| GMP001 | **Title:** Posology in children oral liquid medication studies in Liberia<br>**Jacob Kolawole**, University of Liberia, Nigeria |
| GMP002 | **Title:** Buccal drug formulation – Pharmacokinetics of Verapamil and its metabolite norverapamil<br>**Wiesław Sawicki**, Medical University of Gdansk, Poland |
| GMP003 | **Title:** Increase and effectiveness in the activity of audits of quality in the center of genetic engineering and biotechnology<br>**Mariela Díaz Cinza**, Havana University, Cuba |

**Lunch Break @ Foyer**

# Organizing Committee Members



**Kenneth Christie**
VTS Consultants, Inc., USA

**Mohammed R Khan**
Synergex Consulting, Canada





**Boyd L Summers**
BL Summers Consulting LLC, USA

**Ramakrishna Pidaparti**
Wipro Technologies, USA





**Daniele Rubert Nogueira**
Federal University of Santa Maria, Brazil

**Wael Mohamed Ebied**
Sedico Pharmaceuticals, Egypt





## Mohammed R Khan

Synergex Consulting, Canada

**Title: Planning to outsource Manufacturing: Have you done your Homework?**

### Biography

Mohammed Khan is a Quality Management Consultant and Principal Synergex Consulting in Ontario, Canada. He has earlier served as Director QA, QC & Regulatory Compliance with DuPont Pharmaceuticals, Canada, and on the Board of the Pharmaceutical Manufacturers Association of Canada, Plant Operations Section. He has also served on the DIA's Advisory Council of North America and chaired the DIA's Canadian Programming Steering Committee and is the recipient of the DIA Outstanding Service Award. He has served as Program Coordinator, Program Committee Member, Session Chair and Speaker at numerous national and international DIA events, as well as Presenter for the PDA, OMICS Group, IQPC, PSG Canada, UK based International Society of Ethnopharmacology, and the Indian Pharmaceutical Congresses.



## Boyd L Summers

BL Summers Consulting. LLC, USA

**Title: Ensure Quality Assurance for Companies and Institutions**

### Biography

Boyd L Summers has completed his Bachelor of Science (BS), Business Administration at Weber State University, USA. His areas of emphasis are: Information Systems, Production and Operations Management, Quantitative Analysis and Methods, Human Resources, Economics, Business Management and Statistical Analysis and Computer Science. He is currently working as a Software Technology Consultant for BI.summers.consulting.llc located in Seattle, Washington. With 30 years of experience in Software Engineering and a leader of multiple software development teams, he continues to solve complex technical challenges to ensure that system and software engineering problems are addressed, resolved and compliant. He is the author of the two software technology books titled; "Software Engineering Reviews and Audits." and "Effective Methods for Software and Systems Integration. He provides Software Articles to Software Engineering Journals and magazines. He was a Speaker at OMICS conferences and is a member of the American Society Quality (ASQ).



## Kenneth Christie

VTS Consultants, Inc., USA

**Title: Current FDA Audit Trends and Most Common Cited Drug GMP Deficiencies**

### Biography

Kenneth Christie has over 30 years of sterile manufacturing and regulatory GMP consulting experience in the areas of Quality Assurance and Validation Management in the pharmaceutical and biotechnology industries. Specifically, his responsibilities include quality system auditing, GMP training, and serving as a subject matter expert for aseptic manufacturing processes, equipment and utilities, medical devices, and solid dosage processes on a global basis. He also performs vendor audits, site pre-approval inspections and assists clients with addressing and correcting regulatory observations. He was the Validation Manager at Parke-Davis' Sterile Products Facility where he was involved in the review and approval of all facilities, equipment, and system commissioning/qualification activities. He had routine interaction with the FDA and European inspectors (EMEA), corporate management and third party contract-manufacturing representatives. He is a speaker and trainer for several professional organizations in the US, Canada, Europe, and Asia and is a published author of several articles dealing with the challenges of aseptic processing. Additionally, he has served as a member of the ISPE's Professional Certification (PCC) Commission as an Examination Development Committee (EDC) member.



## Danuta Radzioch

McGill University, Montreal and Scientific Officer, Laurent Pharmaceuticals Inc., Canada

**Title: Importance of characterization of variation in the secondary endpoint measures prior to the trial: a key to a successful outcome of phase 1 trial and progression to a phase 2 stage of the study**

### Biography

Danuta Radzioch has been a member of Infection and Immunity Global Health Axis and Medical Genetics and Genomics Axis within the Centre for the Translational Biology and Centre for Innovative Medicine at the McGill University Health Centre. She brings expertise in molecular biology, host-pathogen interactions, mouse models and translational medicine. Dr. Radzioch is a Fulbright Scholar, is a recipient of numerous prestigious awards, including several career awards and research grants from FRSQ (Fonds the Recherché Santé Québec), Canadian Institute of Health Research (CIHR), US Department of Defense (DoD) and the American Asthma Foundation-Sandler Program for Asthma Research (SPAR; Senior Investigator Award) and Quebec Consortium for Drug Discovery (CQDM) and Ministère de l'Enseignement supérieur, Recherché, Science et Technologie (MESRST). Following postdoctoral training at the National Cancer Institute, NIH she has joined Faculty of Medicine at McGill in 1989 and since 2003 is a full Professor at the Department of Medicine and Human Genetics.

## Dharmi Trivedi

Professional Pharmaceutical Quality and Compliance Specialist, USA

**Title: Stability considerations from early stage development through Phase-IV of Pharmaceutical drug products**

### Biography

Dharmi has Master's degree in science majoring in Chemistry from Saurashtra University, India. Dharmi is a professional pharmaceutical Quality and Compliance specialist. Dharmi has over 20 years of experience in Pharmaceutical Industries including, Quality and Compliance, Quality Control and Research and development. During her career she has gained expertise in cGMP areas that include; investigations, CAPAs, change control, process validation, Quality Management System (QMS),Third party Organization (TPO) management, stability program, and external/internal audits.



## Nadia Narine

Lumar Food Safety Services Ltd., Canada

**Title: Traceability Guide for General Food manufacturers**

### Biography

Nadia has 18 years of experience in various Quality Assurance/Technical roles. She has worked within a variety of food manufacturing facilities, as well as retail, which include industry's such as bakery, confectionery and dairy. Nadia has expertise in Quality Assurance, Quality Control, food safety, and hygiene. She has strong audit and training skills. She is currently an approved auditor for GFSI standards such as BRC and SQF. In addition she is a current auditor to unaccredited standards such as the Gluten Free certification program, GMASAFE, HACCP, and GMP. Nadia is a BRC Approved Training Provider for Food and Storage & Distribution, and Agents and Brokers. Also a Lead Instructor for FSPCA Preventive Controls for Human Food . She is an auditor to (accredited and unaccredited) food standards and a certified consultant for SQF. Nadia's educational background includes Industrial Microbiology, Marketing, Six Sigma, and ongoing courses for professional development in food safety. She is currently a member of The American Institute of Quality, and IAFP. Nadia is currently the Owner/President of Lumar Food Safety Services Ltd.



## Peggy J Berry

Synergy Consulting LLC, USA

**Title: Good Clinical Practices**

### Biography

Peggy J. Berry, MBA, RAC, is the President & CEO at Synergy Consulting where she provides consulting services to companies in all aspects of drug development. She also provides group and one-on-one training in drug development, regulatory affairs and project management topics. Prior to founding Synergy Consulting in 2015, she was Vice President of Regulatory Affairs at Insmed where she was responsible for the development and implementation of global regulatory strategies and the management and oversight of the regulatory affairs department. Prior to Insmed, she was Vice President of Regulatory Affairs and Quality at Amarin. She has also held a variety of senior level positions at Dyax (now Shire), MGI Pharma (now Eisai), AstraZeneca, and Dey Pharma (now Mylan). She has also held Regulatory Affairs roles within two clinical contract research organizations (ILEX Oncology and Cato Research Ltd) and has worked in review divisions at the FDA. In addition, Ms. Berry consults for a number of companies in the regulatory and quality area, conducts a number of training courses, and is active in the Regulatory Affairs Professionals Society. She is the editor of the 2010 book "Choosing the Right Regulatory Career" (RAPS, MD) and author of the 2011 book "Communication & Negotiation" (RAPS, MD).



## Rashid Mahmood

Surge Laboratories Private Limited, Pakistan

**Title: Quality Risk Management**

### Biography

Rashid Mahmood has 13 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, NDA, ANDA, BLA, GMP Requirements, Drugs Laws, Statistical Methodology, Method Validation, Process & Cleaning Validation, Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, ISO/IEC 17025:2005, 14001:2004, OHSAS 18001:2007, SA 8000 and 9001:2008 with strong scientific, analytical, statistical, planning, managerial and training skills, have written several articles and attended many international conferences as a speaker and presented various speeches in USA & China on Clean ing Validation, cGMP Guidelines, Quality Risk Management etc.



## Ramakrishna Pidaparti

Wipro Technologies, USA

### Biography

Rama K Pidaparti has over 25 years of industry experience. He has a M.S in computer science and Healthcare and Life Sciences courses from Sloan School of Management. He has worked on regulatory compliance aspects from concept to post market, at multiple Life Sciences businesses such as GE Health care, Boston Scientific, Medtronic, Zimmer, Johnson and Johnson, Genzyme, Genetec, Millennium Pharmaceuticals. He is a seasoned speaker on Compliance related topics at Life Sciences events.



## Jerry Lanese

The Lanese Group, Inc., USA

**Title: Turning the FDA Quality Metrics into a Proactive Quality Improvement Tool**

### Biography

John G. (Jerry) Lanese, Ph.D, is an independent consultant in the area of quality systems, quality management and FDA regulatory compliance. He has more than thirty years of experience in quality systems, quality system development, quality system audits, method development, quality control laboratory management, quality assurance, regulatory compliance and training. Jerry has a thorough knowledge of Baldrige Criteria, FDA Quality System approach, Quality System Regulation, ISO 13485, analytical instrumentation, product testing, specification development, validation, documentation review, GMPs, and quality management concepts. Jerry is currently the co-editor of GXP Talk, a continuing series of articles that appears in the Journal of Compliance.



## Wael Ebied

SEDICO Pharmaceutical, Egypt

**Title: Bioavailability and Bioequivalence concerns in Pharmaceutical Industry**

### Biography

Wael Ebied has completed his BPharm from Tanta University with Postgraduate studies from Al-Azhar University School of Pharmacy. He is a certified Senior Professional, SQA Services Inc., US leader in providing supply chain management, quality and engineering services to pharmaceuticals, medical devices and highly regulated industries. He has published many papers in reputed journals and has been serving as an Editorial Board Member of repute. He has more than twenty years' experience in pharmaceutical industries, biotechnology, medical devices and APIs. He is an accomplished technical presenter with numerous projects, scientific publications, participated in some patents and was awarded many premiums.



## Reza Shojaei

Canadian Plasma Resources, Canada

**Title: GMP Requirements for Canadian Blood & Blood Establishments**

### Biography

Reza has over 18 years of experience in quality management and establishing of medical diagnostic systems, blood and plasma screening laboratories and source plasma collection centres. Reza started working in Canadian Plasma Resources in 2009 where he designed a unique and Canadian oriented Quality Systems Management for the source plasma collection centers in Canada. Currently he is responsible to ensure that every individual human plasma unit, collected by way of an established automated apheresis process, and released for sale from a corporation-controlled facility, meets current quality and safety requirements of both Canadian Plasma Resources and Health Canada.