



GENERICS & BIOSIMILARS

# PPM SUMMIT WORLD TOUR

GENERICS & BIOSIMILARS  
PROJECT, PROGRAM, AND PORTFOLIO  
MANAGEMENT SUMMIT

**FOCUS:** GENERICS & BIOSIMILARS

**FEBRUARY 25-26, 2021  
ONLINE VIA HOPIN**

# CORE TOPICS

1. Value added medicines
2. The rise of complex generics
3. Biosimilars – optimizing market access
4. Developing products that qualify for multiple markets
5. Effective product launch planning and execution
6. Manufacturing innovations – improving productivity
7. Managing risk, legal, regulatory, and compliance issues from the perspective of portfolio and project managers





# SPEAKERS



Chairperson

## Sameer Agarwal

CEO & Managing Partner  
CSA Healthcare  
Germany



## Stephanie Amend-Mall

Global Project Manager  
Sandoz



## Bahadir Cakmak

Global Portfolio Pipeline Manager  
Sandoz  
Germany



## Reethu Patel

Global Product Launch Manager  
Sandoz  
Germany



PPM Practice Manager | Enterprise Architect |  
Intercultural Enthusiast | International Speaker  
France



## Klemen Spaninger

Senior Director, Head of Project Management  
Office  
Global Program Lead  
Fresenius Kabi  
Switzerland



## Ana Gavaldá

Portfolio Management Specialist  
Anion  
Spain



## Yasser Gawad

Associate Director  
R&D Project Management  
Teva Pharmaceuticals  
United States



## Lalit Baregama

General Manager  
Global Business Development  
Cadila Pharma  
India



## Erez Hybloom

Independent Consultant  
former Global & Europe  
Commercial Portfolio Management  
Teva  
Netherlands



## Michal Urban

Project Management &  
Launch Preparation Lead  
Sanofi  
Czech Republic



## Marjan Dzeperoski

Regulatory Affairs and Pharmacovigilance  
Manager  
Bionika Pharmaceuticals  
Macedonia



## Paras Vasanani

Director & Head  
Business Development, Portfolio Strategy  
Kashiv Biosciences  
India

# SPEAKERS



## Daniela Braun

Senior Director Project Mangement  
Celonic Group  
Switzerland



## Pallavi Trivedi

Head of Regulatory Affairs  
Warwick Healthcare  
United Kingdom



## Edric Engert

Managing Director  
Abraxeolus Consulting  
United States



## Detlef Bahrens

Founder  
Baypharma  
Germany



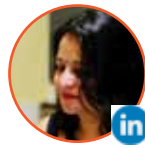
## Varada Bapat

Associate Vice President  
Project Management  
Wockhardt  
India



## Rachna Khanna

Head Product Portfolio  
Dr. Reddy's Laboratories  
India



## Neelu Goel

Associate Director- Regulatory  
Affairs & Compliance  
Emcure  
India



## Dinesh Kundu

Co-founder & Director  
QbD Biosciences  
India

# THURSDAY

February 25, 2021

9:30 **KEYNOTE: NEW TRENDS IN THE FIELD OF BIOSIMILARS & GENERICS**  
Though confronted by a tough capital market outlook and a multitude of challenges, generics companies can still generate substantial value and capitalize on abundant growth opportunities. Should they risk the uncertainties of the biosimilars opportunity, try to crack the respiratory market, focus on the stable OTC arena, or pursue differentiation in sterile injectables? Choosing the right opportunities is equally crucial when deciding where to compete, and rather than trying to establish a presence in every market from Africa to China, companies should focus on countries where they believe they can succeed. To emerge as winners, they need to make clear judgments about products and markets, forge partnerships, and join forces and invest in building new capabilities.

**Sameer Agarwal**, CEO & Managing Partner  
**CSA Healthcare, Germany**

10:00 **CASE STUDY: OPPORTUNITIES AND CHALLENGES FOR DIFFERENT GENERIC DRUG TYPES**

What Project and Portfolio Managers need to do to succeed in markets of different Generic drug types. We discuss the opportunities these markets are providing, what are the major challenges, and how to tackle them.

- Oral Solids
- Sterile Injectables
- OTC

**Stefanie Amend-Mall**, Global Project Manager  
**Sandoz**

10:30 NETWORKING BREAK

11:00 **PANEL DISCUSSION: 505(b)(2) HYBRID DRUGS OPPORTUNITIES**

There is great potential in the 505(b)(2) pathway. The key is being selective and strategic about which products to develop, and then creating a careful plan for submission and launch

- How can companies evaluate the potential for 505(b)(2) products?
- What are the essentials for the right planning and strategy for 505(b)(2) products to increase & harness the potential for strong sales and ROI?
- What are the key considerations of 505 (b)(2) projects when Managing Pharma Portfolio?
- Usually differentiated generics have not been very successful in Europe vis-a-vis USA. What can be done to be more successful in Europe?

**Ana Gavaldá**, Portfolio Management Specialist  
**Annion, Spain**

**Paras Vasanani**, Director & Head Business Development,  
Portfolio Strategy, **Kashiv Biosciences, India**

11:30 **PRESENTATION: VALUE ADDED MEDICINES OPPORTUNITIES**

- Understanding Value Added Medicines
- Overview of opportunities Value Added Medicines are bringing
- Key aspects of successful Value-Added Medicines in Generics portfolios
- Risk Management fundamentals for Value Added Medicines
- Specifics of different markets (US, Europe, Asia)

**Ana Gavaldá**, Portfolio Management Specialist  
**Annion, Spain**

12:00 NETWORKING LUNCH

13:00 **PANEL DISCUSSION: REGULATORY CHALLENGES OF COMPLEX GENERICS AND COMBINATION PRODUCTS AND HOW TO DEAL WITH THEM**

- What are specific EU-MDR Challenges for Combination Products and how to deal with them?
- What are specific regulatory Challenges for complex generics in different regions?
- What are the regulatory disparities existing among regulatory agencies in US and Europe for complex generics?
- In your experience which are the best practises for ANDA submissions without product-specific guidance?

**Pallavi Trivedi**, Head of Regulatory Affairs  
**Warwick Healthcare, United Kingdom**

**Marjan Dzeperoski**  
Regulatory Affairs and Pharmacovigilance Manager  
**Bionika Pharmaceuticals, Macedonia**

**Neelu Goel**, Associate Director- Regulatory Affairs & Compliance, **Emcure, India**

13:30 **KEYNOTE: BIOSIMILARS – OPTIMIZING MARKET ACCESS**

- Launch planning in Biosimilars
- Overview and comparison of risks vs. returns
- High-level framework and tools to manage risks and optimize market access
- Deep-dive into commercial considerations in the U.S.
- Overview of less regulated markets with challenges and opportunities

**Klemen Spaninger**, Senior Director, Head of Project Management Office, Global Program Lead  
**Fresenius Kabi, Switzerland**

14:00 **PANEL DISCUSSION: BIOSIMILARS – OPPORTUNITIES, CHALLENGES, AND OUTLOOK**

- How should companies compare market opportunities for biosimilars in Europe, US and emerging markets?
- How to find, evaluate and plan for biosimilars market opportunities?
- What are the key factors influencing the biosimilars entry decisions?
- What are the regulatory challenges and differences between US, EU and emerging markets?
- What are the major development challenges for biosimilars and how to tackle them? If you can give some high level tips please.

**Paras Vasanani**, Director & Head Business Development,  
Portfolio Strategy, **Kashiv Biosciences, India**

**Edric Engert**, Managing Director  
**Abraxeolus Consulting, United States**

**Klemen Spaninger**, Senior Director, Head of Project Management Office, Global Program Lead  
**Fresenius Kabi, Switzerland**

**Dinesh Kundu**, Co-founder & director  
**QbD Biosciences, India**

14:30 NETWORKING BREAK

# THURSDAY

February 25, 2021

15:00 **PANEL DISCUSSION: DEVELOPING PRODUCTS THAT QUALIFY FOR MULTIPLE MARKETS**

- How can we develop products that qualify for different markets?
- How to tackle regulatory challenges of developing products that would qualify for multiple markets?
- How to create Strategic Alliances to develop products that qualify for multiple markets
- What B2B strategies to Break Commercialising and Marketing Barriers you have experience with?
- Can you share In/out-licensing tips to create a robust portfolio suitable for different markets?

**Klemen Spaninger**, Senior Director, Head of Project Management Office, Global Program Lead  
**Fresenius Kabi, Switzerland**

**Marjan Dzeperoski**, Regulatory Affairs and Pharmacovigilance Manager, **Bionika Pharmaceuticals, Macedonia**

**Lalit Baregama**, General Manager - Global Business Development, **Cadila Pharma, India**

**Dinesh Kundu**, Co-founder & director  
**QbD Biosciences, India**

15:30 **PANEL DISCUSSION: BUILDING TOP NOTCH ALLIANCE NETWORKS**

- How to create a balanced portfolio between development and external opportunities.
- How to assess the benefits of outsourcing/out-licensing high- valuable products
- What does partnership mean in the licensing business?

**Detlef Bahrens**, Founder, **Baypharma, Germany**

**Lalit Baregama**, General Manager - Global Business Development, **Cadila Pharma, India**

16:00 **WORKSHOP: “SECRETS OF SUCCESSFUL PROJECT TEAMS: MANAGING BIAS IN PROJECT ORGANIZATIONS FOR EFFICIENT DECISION-MAKING”**

*Duration: 45 – 60 minutes (can be adapted to the agenda)*

Description: Accelerating change of technology, quicker response times and changing requirements are some of the drivers that are pushing businesses worldwide to embrace business agility. Post-COVID-19 crisis trends are progressively encouraging remote work and a move towards digitalisation. Most project teams created under such circumstances are temporary ‘organisations’ composed of cross-functional members, pushed prematurely into working virtually. The result is frequent project failures, due to erroneous decision-making and risk attitude of contributing teams. A cognitive bias is a systematic error in thinking that affects decisions and judgments that people make. Juggling between proven best practices and new circumstances requiring changes in our way of working, make us feel uncomfortable. Frequently-asked questions of project leaders include: How to select between different implementation scenarios? What invisible errors of judgement and assumptions you take for granted, could be contributing to your choice of technology or solution? What level of detail in reporting to provide to Stakeholders? How to stay result-oriented and still not forget the human aspects of projects? Staying inclusive and open to other perspectives and solutions make you a mindful leader who can deliver successful corporate initiatives in challenging times. If you wish to explore the link between the rational and the irrational side in managing projects, if you wish to spot possible errors, gaps or flaws in your decision-making, and develop an approach to avoid, overcome or fix them, then this workshop is for you.

**Mithun Mridha**, PPM Practice Manager | Enterprise Architect | Intercultural Enthusiast, International Speaker, **France**

Biography: Mithun Mridha is PPM Practice Manager and Enterprise Architect based in Paris. He also happens to be an Intercultural Enthusiast and an International Speaker. He helps Senior Executives to foster strategic alignment, improve project performance and develop future leaders. He has successfully served multinationals from diverse sectors and has extensively travelled in 60 countries. He has lived and worked for long periods of time in four countries. Mithun has taught International Business and Project Management at the following prestigious European Schools – ENPC ParisTech, Paris Dauphine, ESSCA, EM Normandie, SDA Bocconi and Freie Universität Berlin.



# FRIDAY

February 26, 2021

- 9:30 **CASE STUDY: JOINT DEVELOPMENT GENERIC PROJECTS BETWEEN TWO COMPANIES - HOW TO ACHIEVE COMMON OBJECTIVES AND SATISFY BOTH PARTIES?**
- A case study - lessons learnt from executing a joint development project - A Project manager's perspective.
  - Development agreement between two parties vs. reality.
  - Alignment on the project strategy while targeting different launch dates due to different IP limits - regulatory, clinical development, API & FP sourcing.

**Michal Urban**, *Project Management & Launch Preparation Lead*, **Sanofi, Czech Republic**

- 10:00 **KEY ELEMENTS OF TRANSITION FROM PORTFOLIO SELECTION TO LAUNCH EXECUTION - ONE OF THE SUCCESS FACTORS FOR BEING A DAY 1 OR FIRST TO MARKET**
- Most of the companies fail to make a smooth transition due to complex internal processes and loss of key knowledge during this phase.
  - Insight on importance of checkpoints during transition, key Challenges and practices

**Reethu Patel**, *Global Product Launch Manager*  
**Sandoz, Germany**

10:30 NETWORKING BREAK



11:00 **PANEL DISCUSSION: INTERNAL COOPERATION TO ENSURE SUCCESSFUL PRODUCT LAUNCH**

We will show how Portfolio Selection, Project Management and Product Launch work together in Sandoz

- What is the role of Portfolio Manager and how is involved in cooperation with Global Project Management and Product Launch?
- What is the role of Global Project Manager and how is involved in cooperation with Portfolio Management and Product Launch?
- What is the role of Product Launch Manager and how is involved in cooperation with Portfolio Management and Global Project Management?
- Which risks are usually delay a launch and how can you mitigate them?
- How to set up Supply chain early on in the right way?
- How to consider the patent situation?
- What does influence volume forecasts?

**Reethu Patel**, *Global Product Launch Manager*  
**Sandoz, Germany**

**Bahadir Cakmak**, *Global Portfolio Pipeline Manager*  
**Sandoz, Germany**

**Stefanie Amend-Mall**, *Global Project Manager*  
**Sandoz, Germany**

11:30 **CROSS INDUSTRY PANEL DISCUSSION: INTERNAL COOPERATION TO ENSURE SUCCESSFUL PRODUCT LAUNCH**

How do you assess the internal alignment between these functions?

- Portfolio Selection
- Project Management
- Product Launch

How do you identify, mitigate, and avoid (if possible):

- the risk of a launch delay,
- the risk of pricing reference,
- pre-launch variations
- variance in the forecasts and country demands, etc.

**Reethu Patel**, *Global Product Launch Manager*  
**Sandoz, Germany**

**Bahadir Cakmak**, *Global Portfolio Pipeline Manager*  
**Sandoz, Germany**

**Stefanie Amend-Mall**, *Global Project Manager*  
**Sandoz, Germany**

**Michal Urban**, *Project Management & Launch Preparation Lead*, **Sanofi, Czech Republic**

**Klemen Spaninger**, *Senior Director, Head of Project Management Office, Global Program Lead*  
**Fresenius Kabi, Switzerland**

12:00 NETWORKING LUNCH



13:00 **KEYNOTE: DIGITAL HEALTH AND GENERICS/ BIOSIMILARS BUSINESS**

**Erez Hybloom**, *Independent Consultant, Former Global & Europe Commercial Portfolio Management*  
**Teva, Netherlands**

13:30 **PANEL DISCUSSION: PRODUCTIVITY AND EFFECTIVITY - MOST OFTEN DELAYS IN GENERIC FORMULATION PROJECTS**

- What are the most often reason for delays in generic formulation projects?
- How to avoid them from perspectives Portfolio and Project Managers

**Yasser Gawad**, *Associate Director, R&D Project Management*,  
**Teva Pharmaceuticals, United States**

**Daniela Braun**, *Senior Director Project Management*  
**Celonic Group, Switzerland**

**Rachna Khanna**, *Head Product Portfolio*  
**Dr. Reddy's Laboratories, India**

**Varada Bapat**, *Associate Vice President, Management*  
**Wockhardt, India**

14:00 **PRESENTATION: ACQUISITION AND OWN LAUNCH OF NICHE PRODUCTS**

- Outlicensing strategy
- High price versus low price markets – value and parallel imports
- Strategy to inlicense projects – risk versus potential

**Detlef Bahrens**, *Founder*, **Baypharma, Germany**



# FRIDAY

February 26, 2021

14:30 **PANEL DISCUSSION: EMERGING MARKETS: OVERVIEW OF EMERGING MARKETS PANEL DISCUSSION**

- APAC
- Middle East
- Russia
- Turkey
- What are the opportunities these markets are providing?
- What are the major challenges and how to tackle them?
- What Project and Portfolio Managers need to do to succeed in emerging markets?
- Generic market: How are generic products positioned in that market?
- Regulatory aspects: How easy/difficult is it to get approval for a generic product in this market? Which special data do you need? CoPPs needed?
- Special requirements: e.g. is local production needed? What does this mean for a project?
- Patent law and enforcement in these markets (How strong are patents? Difference between primary and secondary patents? Patent linkage?)

**Stefanie Amend-Mall**, *Global Project Manager*, **Sandoz**

**Michal Urban**, *Project Management & Launch Preparation Lead*, **Sanofi, Czech Republic**

15:00 NETWORKING BREAK

