AGENDA



³ 2022

21 June - Americas & Europe 22 June - Asia Pacific

8:00 AM EDT | 1:00 PM BST | 9:00 AM IST

Introduction & Welcome Keynote
Christian Marcazzo (General Manager,
IDBS)

8:30 AM EDT | 1:30 PM BST | 9:30 AM IST

Trends in Research and Key Challenges

Matthew Clifford (Director of Research & Innovation, IDBS)

9:00 AM EDT | 2:00 PM BST | 10:00 AM IST

How customer ideas drive IDBS' product development priorities - IDBS Ideas Portal Stuart Ward (Director of Platform and Solutions, IDBS)

9:30 AM EDT | 2:30 PM BST | 10:30 AM IST

The integration conundrum resolved

David Levy (VP of Strategy

& Partnerships, Scitara)

Craig Williamson (Platform Product Owner
Integrations, IDBS)

10:30 AM EDT | 3:30 PM BST | 11:30 AM IST

My five critical learnings as business owner of E-WorkBook
Doug Scheesley (Scientific Leader Business Owner, IDBS E-Workbook, GSK)

11:30 AM EDT | 4:30 PM BST | 12:30 PM IST

Alberto Pascual (Director Data Science

& Analytics, IDBS)

Vyshnavi Bhyravajosula (Data Scientist, IDBS)

1:30-2:30 PM IST

Additional Q&A for APAC

Rohit Ghosh, (Customer Success Manager, IDBS)

Satyalakshmi Oruganty (Lead - Business

Consulting, IDBS

22 June - Americas & Europe 23 June - Asia Pacific

8:00 AM EDT | 1:00 PM BST | 9:00 AM IST

Accelerating time-to-insight
Pietro Forgione (Vice President, Strategy,
Marketing and Product, IDBS)

8:30 AM EDT | 1:30 PM BST | 9:30 AM IST

How to build foundations to enable insights

Marc Smith (Director of Strategic Solutions,

IDBS)

9:00 AM EDT | 2:00 PM BST | 10:00 AM IST

Moving from hindsight to foresight (descriptive analytics to predictive and ultimately prescriptive analytics)

Alberto Pascual (Director Data Science & Analytics, IDBS)

Francois Zimmermann, EMEA Field CTO, Tableau)

10:00 AM EDT | 3:00 PM BST | 11:00 AM IST

Laying the foundation for accelerated tech transfer

Chris Mayhew (Accenture)

Graeme Moody (Program Manager, BioPhorum)

Scott Weiss (VP BD & Innovation, IDBS),

Teodor Leahu, (Director of European Operations, IDBS)

Bob Dvorak (Principle, BDMS Consulting)

11:00 AM EDT | 4:00 PM BST | 12:00 PM IST

Smarter, Faster, Better Validation Ryan McGee

(Associate Director, Bioanalysis, Incyte)

Merry Danley (Director Operational

Effectiveness, Q2 Lab Solutions)

Dan Curtis (Cloud Validation Services, IDBS)

Jim Brooks (GxP Solution Owner, IDBS)

12:00 PM EDT | 5:00 PM BST | 1:00 PM IST

Meet the 3 Pillars of Polar Solutions Consulting Team

2:00-3:00 PM IST

Additional Q&A for APAC

Rohit Ghosh, (Customer Success Manager, IDBS)

Satyalakshmi Oruganty (Lead - Business

Consulting, IDBS

23 June - Americas & Europe 24 June - Asia Pacific

8:00 AM EDT | 1:00 PM BST | 9:00 AM IST

Fireside Chat: Why is PIMS critical to ensuring IDBS can help BioPharma bring life-changing therapies to market faster?

Bob Di Scipio (Former CEO, Skyland Analytics)
Christian Marcazzo (General Manager, IDBS)

9:00 AM EDT | 2:00 PM BST | 10:00 AM IST

Your journey to the cloud

Chris Ovett (SaaS Cloud Project
Manager, IDBS), Bharat Swain (Technical
Project Manager, GPS, IDBS)
Arnaud Muzaton (Technical Lead, GPS, IDBS),
Angus Tosh (SRE Manager, IDBS)

10:00 AM EDT | 3:00 PM BST | 11:00 AM IST

Best Practices on building and implementing a digital process data strategy

Matt Wheeler (Validation Manager,

Precision Biosciences)

Eric Dahlgren (Director of MST, Alnylam)

Margaret Mayo (Process Monitoring

Specialist II, Bluebird Bio),

Rahul Kaushik, (Senior Vice President,
Pharmaceutical Development, Technical &
Manufacturing Operations, FibroGen)
Scott Weiss (VP BD & Innovation, IDBS)

11:00 AM EDT | 4:00 PM BST | 12:00 PM IST

Skyland PIMS Use Case demonstration
Ken Forman, David Brick, Mallory Turner,
Sep Mohseni (PIMS Specialists, IDBS)

12:00 PM EDT | 5:00 PM BST | 1:00 PM IST

Closing Note

Christian Marcazzo
(General Manager, IDBS)

1:30-2:30 PM IST

Additional Q&A for APAC

Rohit Ghosh, (Customer Success Manager, IDBS)

Satyalakshmi Oruganty (Lead - Business

Consulting, IDBS

8:00 AM EDT | 1:00 PM BST | 9:00 AM IST Introduction & Welcome Keynote



Christian Marcazzo

General Manager, IDBS

Christian Marcazzo has been the General Manager of IDBS since 2018, leading the business through a period of transition, investment and growth as a Danaher Operating Company. Prior to joining IDBS, Christian has spent 25 years at the interface of biology and software, leading organizations like Perkin Elmer, Spotfire and LION bioscience through the genomics revolution and the digitization of R&D. He has a BA in Molecular and Cell Biology from the University of California, Berkeley and is based at the IDBS headquarters in Surrey, UK.

8:30 AM EDT | 1:30 PM BST | 9:30 AM IST Trends in Research and Key Challenges

About the Session:

In a fast moving market place, which is evolving into an Insilco driven discovery market, there are a whole range of different technologies, companies and methods used across the world. In this session explore trends in research, key challenges and the digital strategies you need for next generation research and innovation. A strategy without an outcome is just an idea, explore how to take your strategies to execution.



Matthew Clifford Director of Research & Innovation, IDBS

Matthew Clifford is Director of Research and Innovation at IDBS, with a remit to bring to market innovative solutions to support IDBS' customers. With over 20 years' experience working within and alongside the pharma industry, including eight years in informatics roles in a top 20 pharma supporting discovery and preclinical organizations, he has a proven background in industry trends and solutions.

9:00 AM EDT | 2:00 PM BST | 10:00 AM IST How customer ideas drive IDBS' product development priorities - IDBS Ideas Portal

About the Session:

One of IDBS' and Danaher's core values is: Customers Talk, We Listen! IDBS launched its Ideas Portal in 2021 as part of an initiative to obtain customer feedback on the Ideas that are going to provide the most value and provide greater visibility on Idea / Enhancement progression into IDBS Products. In this presentation the following will be covered:

- An update on IDBS' Ideas Portal following its launch 12 months ago.
- How Ideas make it into IDBS' Roadmap and Products.
- Which Ideas have been delivered in IDBS Products?
- Delivering Ideas during i³!



Stuart WardDirector of Platform and Solutions, IDBS

Stuart is Director of Platform and Solutions and responsible for ensuring that IDBS products meet the needs of customers. He has grown the IDBS Platform team, which includes Product Owners, User Experience Designers and Technical Authors, so that it can provide the necessary business and domain experience required to create software and solutions to enable BioPharma and other industries achieve faster scientific breakthroughs. In addition, he led the creation and launch of The E-WorkBook GxP Cloud, which was IDBS' first

SaaS product for use in regulated (21 CFR Part11, GxP) environments. Before starting this role in January 2014, he was Product Manager for E-WorkBook for four years and worked in IDBS Global Professional Services for five years, responsible for deploying IDBS' products both from a technical and project management perspective. Prior to working at IDBS, Stuart completed a Post-Doctoral fellowship at the NIH and then worked for Ionix Pharmaceuticals. Stuart obtained his PhD in Pharmacology from the MRC National Institute for Medical Research (University of London).

9:30 AM EDT | 2:30 PM BST | 10:30 AM IST The integration conundrum resolved

About the Session:

The volume of data generated in modern laboratory environments is constantly increasing, as is the number and variety of instruments and systems producing that data. There are universally accepted benefits to automating the transfer of data from its myriad points of origin to where it is required, but how can we provide our scientists & informatics managers the agility they need to keep up with the relentless change, and ensure their critical workflows are supported?

Dave Levy VP of Strategy & Partnerships, Scitara

Dave is a well-established product creator and evangelist. In his 30+year career in product and global account management, he has introduced several game-changing products to market.





Craig Williamson Platform Product Owner - Integrations, IDBS

Craig is an organic chemist by training and has enjoyed a prior career in research & development creating novel drug candidates and developing formulations to combat Alzheimer's disease. In his current role as a Platform Product Owner at IDBS, Craig is responsible for ensuring that the IDBS platform provides a powerful and comprehensive suite of programming interfaces to enable our diverse community of customers and partners to easily

connect their IDBS products to the other assets in their R&D workflows. Craig is also responsible for IDBS' out-of-box integrations to common informatics systems including Chromatography Data Systems (CDS) & Scientific Data Management Systems (SDMS).

10:30 AM EDT | 3:30 PM BST | 11:30 AM IST My five critical learnings as business owner of E-WorkBook

About the Session:

Replacing your ELN products with a new product is one thing. Trying to fundamentally change the role of the ELN within your company is another. In this talk, I will share with you my five most critical learnings picked up during the process of deploying IDBS E-WorkBook that fits into a world that demands data reusability.

These five critical learnings are:

- 1) The importance of democratization of data
- 2) Asking yourself if it is a tool or a toy
- 3) Moving away from the paper lab notebook mindset
- 4) The importance of demos
- 5) Different approaches to building an end-to-end solution

Doug Scheesley

Scientific Leader - Business Owner, IDBS E-Workbook, GSK

Douglas Scheesley is the business owner for a CMC-wide deployment of IDBS E-WorkBook and influencer in the overall data strategy at GlaxoSmithKline. Starting as an analytical chemist, he has been involved in numerous tech and scientific projects across small and large molecule. Combining his experience in science, coding, multivariate analysis, automation, and project management, Doug is passionate about improving the process of generating scientific knowledge to help the patient do more, feel better, and live longer.



11:30 AM EDT | 4:30 PM BST | 12:30 AM IST Insights and using your data

About the Session:

Ingesting, storing, analysing, and sharing data sets of various types and sizes has never been easier, faster, or more trustworthy in IDBS. Our solutions facilitate the effective analytics journey across your organization and enable democratized, empowered, and faster decision making for your digital transformation journey. In this presentation we will show how this end-to-end process works and how IDBS unlocks the power of data and analytics from beginning to end. We will show live examples for data ingestion, extraction, visualization and advanced analytics.



Alberto Pascual

Director Data Science & Analytics, IDBS

Alberto Pascual is a Doctor in Bioinformatics with a long experience in Data Science and biomedical domains. Graduated in Computer Science, he received a PhD on Bioinformatics from the Autonomous University of Madrid. After some postdoc period, he joined the National Center for Biotechnology (CNB), leading a bioinformatics Research and Core facility group. He also co-founded Integromics, a Bioinformatics start up, in 2003. The company received the Frost and Sullivan European Bioinformatics Project of the Year Award for

2007. The company was acquired by PerkinElmer in 2014, when he served as a Senior Manager AI and Analytics Innovation. Currently he is the Director of Data Science and Analytics at IDBS where he is responsible for developing and executing IDBS' strategy on AI, Data Science and Analytics to deliver novel products and services to our customers in life sciences R&D markets.

Vyshnavi Bhyravajosula

Data Scientist, IDBS

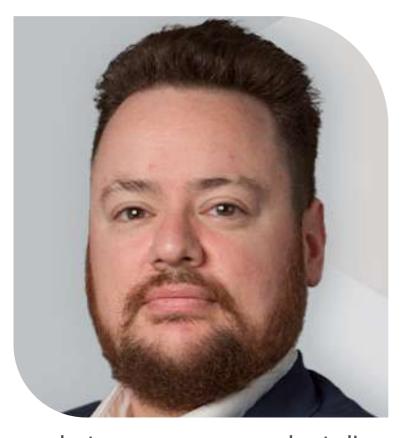
Vyshnavi Bhyravajosula is a Data Scientist at IDBS who is passionate about bringing intelligence through machine learning and enabling data-driven decision making. She is a strong supporter of women in science and technology. Vyshnavi collaborates with



internal and external stakeholders to tackle business questions across industries and utilizes her skills to turn data into insights and actions. Vyshnavi earned her M.S. in Data Science at Northeastern University before joining IDBS, where she worked as a research assistant for two years.

8:00 AM EDT I 1:00 PM BST I 9:00 AM IST Accelerating time-to-insight

In this session we will frame up the importance of time-to-market for new drugs, and explore the impact insight and understanding have in helping to reduce timelines across the BioPharmaceutical lifecycle. There are different approaches to delivering insight, and we will explore the challenges and opportunities as well as the importance of contextualisation.



Pietro Forgione

Vice President, Strategy, Marketing and Product, IDBS

Pietro joined IDBS in 2006 and has more than 18 years of experience in the BioPharmaceutical industry. As Vice President of Strategy, Product and Marketing, Pietro is leading innovation with a focus on accelerating the discovery of breakthrough products and the development of life changing vaccines and therapies.

Pietro has a deep understanding of the way in which digital transformation and data helps drive innovation and time to

market across new product discovery, development and manufacturing.

Pietro has held several roles at IDBS including Head of Global Strategic Sales and Vice-President of Sales, EMEA.

Pietro has a first-class honors degree in Biotechnology from the University of Nottingham.

8:30 AM EDT I 1:30 PM BST I 9:30 AM IST How to build foundations to enable insights



Marc Smith

Director of Strategic Solutions, IDBS

Marc is Director of Strategic Solutions and is accountable for the development of the IDBS Polar BPLM and associated Solutions.

Marc is an expert in laboratory and operational technology, laboratory informatics and system integration and leads a team of technological and domain experts committed to the development of the Polar Solutions.

He has over 15 years of experience working in the pharmaceutical sector implementing and leading digital solutions and strategies.

Before joining IDBS in 2021, he worked at Lonza Biologics and Angel Biotechnology. He holds a BSC (Hons) in Pharmacology from the University of Sunderland.



9:00 AM EDT I 2:00 PM BST | 10:00 AM IST Moving from hindsight to foresight (descriptive analytics to predictive and ultimately prescriptive analytics)

IDBS vision on Insight is the democratization of advanced analytics during the whole Biopharma Lifecycle to provide our customers a better decision making. To this end, we provide augmented analytics capabilities embedded in our platforms with the required functionality to do data access, reporting, visualization, exploration, and advanced analytics. As part of our strategy, we use Tableau as our preferred embedded analytics partner. In this session IDBS and Tableau will provide concepts and use cases levering IDBS and Tableau platforms together to scale AI for enabling augmented, predictive, and prescriptive analytics. We hope these technologies and solutions help scientists, not only to store and manage their data, but also to be able to analyze it, extract insights and take actions.



Alberto Pascual Director Data Science & Analytics, IDBS

Alberto holds a PhD in bioinformatics with a long experience in data science and biomedical domains. Graduated in Computer Science, he received his PhD from the Autonomous University of Madrid. After some postdoc period, he joined the National Center for Biotechnology (CNB), leading a bioinformatics Research and Core facility group. He also co-founded Integromics, a Bioinformatics start up, in 2003. The company received the Frost and Sullivan European Bioinformatics Project of

the Year Award for 2007. The company was acquired by PerkinElmer in 2014, when he served as a Senior Manager AI and Analytics Innovation. Currently he is the Director of Data Science and Analytics at IDBS where he is responsible for developing and executing IDBS' strategy on AI, Data Science and Analytics to deliver novel products and services to our customers in life sciences R&D markets.

Francois Zimmermann EMEA Field CTO, Tableau

Francois Zimmermann is the Field CTO for Tableau in EMEA and focuses on developing the partner ecosystem to solve the end-to-end data challenges that Tableau customers face as they build insights-driven businesses and embed analytics inside every business process. Francois has a background in Analytics, Cloud Services, Data Integration and IoT as well as vertical solutions for Financial Services; Industrial & Manufacturing; and Health & Life Sciences.





10:00 AM EDT I 3:00 PM BST I 11:00 AM IST Laying the foundation for accelerated tech transfer

About the session:

More efficient acceleration of technology transfer has become increasingly important with the advent of precision medicine and increasing regulatory scrutiny into product quality, data integrity and the management of external partners. The primary driver for successful technology transfer is the sharing of accurate and timely product and process knowledge between development and manufacturing and within manufacturing sites.

There are a number of hurdles to achieving the level of process knowledge required for successful technology transfer. Many of these emerge from subpar data management including reliance on spreadsheets and paper records, disparate digital data sources and geographically dispersed teams and sites.

Join us for an engaging dialog between industry experts on how they overcame hurdles to achieve the level of process knowledge required for successful technology transfer and how they are preparing for the shift from static tech transfer to dynamic, persistent and compliant knowledge sharing.



Chris Mayhew Accenture

With 25 years of software development background, Chris has been involved with industry of all shapes and sizes from start-up organisations to larger corporates, leading and managing teams. Over the past 10 years Chris has been growing his expertise in the scientific software arena having worked previously with Accelrys, now the BIOVIA brand with Dassault Systems, having been successfully

promoted from a Solutions Consultant to Senior Manager along the way. Chris joined the Accenture Scientific Informatic Services team in 2019 as a Technology Consulting Manager. Since joining, Chris has provided invaluable insight into the Scientific Informatics landscape and dealing with complex, scientific data

Scott Weiss

VP BD & Innovation, IDBS

Scott Weiss is responsible for developing IDBS' expanding network of technology and channel partners. He joined IDBS in 2004 and has held senior leadership roles in consultancy, product management and strategy. Prior to joining IDBS, Scott spent over 20 years in the pharmaceutical industry, where he led multiple drug-development programs from conceptualization to entry into clinical trials and has authored over 30 peer-reviewed scientific papers and patents. He obtained his PhD in

Psychology from the University of Leeds, specializing in Neuroscience.





Graeme Moody

Program Manager, BioPhorum

Graeme is based in Cambridge UK and has spent 25 years in the pharma industry as a drug metabolism and pharmacokinetics specialist, supporting oncology, respiratory/inflammation and diabetes research programmes. Graeme introduced some of the first robotic liquid handlers into Astrazeneca in the mid1990-s. He is a Lean Sigma Master Blackbelt and has lead numerous business

improvement projects within R&D at Astrazeneca. Graeme has been with BioPhorum for 3 years running projects in the areas of Robotic Technologies, Continuous Biomanufacturing and New Technology Adoption.



Teodor Leahu

Director of European Operations, IDBS

Teodor has 14 years of expertise as a scientist in biotech process development, design, optimization, and validation. His successful track record building and managing technology roadmaps for GMP manufacturing, including software selection, qualification, and implementation, position him as a respected advisor on maximizing operational efficiency to accelerate scale-up, tech transfer, and

commercial release. Before joining IDBS, Teo served as Process Development Scientist at Emergent BioSolutions, where he led science and technology for a newly developed orphan disease vaccine. Previously at Merck Healthcare, his roles spanned Bioprocess Development Scientist and Compliance Specialist for Downstream Processing. Teo holds a BS in Biomedical Engineering from Yale University and an MS in Biotechnology and Bioengineering from EPFL (Swiss Federal Institute of Bioengineering).



Bob Dvorak
Principal, BDMS Consulting

11:00 AM EDT I 4:00 PM BST I 12:00 PM IST Smarter, Faster, Better Validation

About the session:

What does it mean to be smarter, faster, and better at computer system validation? Some examples include leveraging, not duplicating, vendor activities and applying principles of Computer Software Assurance (CSA) to apply critical thinking and eliminate unnecessary documentation. Join us for an engaging dialog between industry experts on the evolution of validation, software as a services (SaaS) considerations, and how to overcome the biggest validation challenges of today.



Merry Danley Director Operational Effectiveness, O2 La

Director Operational Effectiveness, Q2 Lab Solutions

Merry is currently leading an active implementation at Q2 Lab Solutions to harmonize BioAnalytical and Vaccine processes across the various sites as well as combining platforms from lab acquisitions. Prior to joining Q2 Lab Solutions, Merry spent 20 years in clinical laboratory informatics implementations including ELN, LIMS, eTMF, EDC, Lab Instrumentation, EDA, CTMS, QMS, Clinical

Lab and data informatics. She has managed a global validation team as well as supporting global audits for 12 years supporting various platforms across the organization including ELN. This includes regulatory audits from FDA, Swiss Medic, MHRA, Chinese FDA and Canada Health specifically around Bioanalytical informatics including ELN.

Jim Brooks GxP Solution Owner, IDBS

Jim Brooks is the GxP Solution Owner for the IDBS Polar Platform. He is accountable for defining the processes and procedures as well as coordinating and executing the activities required to deliver qualified GxP systems and solutions to our customers. His long-standing years in biopharma where he was responsible 20 career spans over for validating, deploying, and managing laboratory information systems in GxP regulated environments





Ryan McGee Associate Director, Bioanalysis, Incyte

Ryan has enjoyed a +20 year career in Bioanalysis starting as a bench scientist through his current role an Associate Director in the DMPK / Clinical Pharmacology group at Incyte where he leads the Regulated Bioanalytical group. In this role, Ryan is responsible for the overall planning, execution, and quality of bioanalysis in support

of preclinical toxicology through registration studies. Ryan is also

responsible for the operational aspects of the group where he oversees the Sample Management team, Equipment IQ/OQ schedules, and Computer System Validation (CSV).



Dan Curtis

Cloud Validation Services, IDBS

Prior to joining IDBS in 2016 Dan gained experience from a diverse range of industry sectors in both consultative and leadership roles. A career that has spanned 25 years in Software testing and Test Management opens many opportunities to drive change and innovate whether that be on the latest satellite control room software, search engine or e-book publishing and distribution system, requirements and regulations are constantly changing and evolving. One constant has been how to bring something new to the status quo.



IDBS opened yet more new opportunities to innovate, evolving the approach to software validation in SaaS systems. Upon devising and developing the first SaaS automated OQ this has been extended and developed into a revolutionary automated PQ, a step towards continuous validation.

As Manager of Cloud Validation Services, working closely with customers, Quality and Engineering teams leveraging the automation and validation experience from previous roles Dan continues to drive change and efficiencies at IDBS

12:00 PM EDT I 5:00 PM BST I 1:00 PM IST Meet the 3 Pillars of Polar

About the session:

About the session: This session will show highlights of the key functionalities of Polar, the world's first BPLM (BioPharma Lifecycle Management) platform. The highlights will focus on the three pillars of Polar — workflows, integrations, and insight. The product demo will include Polar Bioprocess, Polar Bioanalysis, and Polar HTPD. This session will provide a product showcase to support the product descriptions, values, and messages provided in other sessions of i3.

In addition to this main demo session, please visit one of the Polar Exhibition Booths to discover more Polar product details with one of the IDBS Solutions Consultants.

The Polar demos will be handled by a trio of IDBS Solutions Consultants:



Jeff Tishler

Jeff Tishler joined IDBS in 2001 and is based in Southern California. His focus at IDBS is spread across Polar, E-WorkBook, and ActivityBase. Jeff has a background in analytical chemistry and laboratory automation. Prior to IDBS, Jeff worked at Ciba-Geigy (Novartis) and Zymark (PerkinElmer).

Ajaz Rosul

Ajaz Rosul joined IDBS in 2021 and is based in Manchester, UK. His primary focus at IDBS is Polar Bioanalysis. Ajaz has a background in bioanalysis as a Research Scientist and LIMS from the vendor side. Prior to IDBS, Ajaz worked at companies including Thermo Fisher Scientific and Abbott Informatics.



Michael Barnes

Michael Barnes joined IDBS in 2021 and is based in Florida. His primary focus at IDBS is Polar Bioprocess and Polar HTPD. Michael has a background in molecular biology and prior to joining IDBS, he worked within Pfizer's BioProcess R&D Group, specifically Cell Line Development.

8:00 AM EDT I 1:00 PM BST I 9:00 AM IST Fireside Chat: Why is PIMS critical to ensuring IDBS can help BioPharma bring life-changing therapies to market faster?

About the Session:

Don't miss this session where IDBS' General Manager, Christian Marcazzo, sits down with Bob Di Scipio, Founder and CEO of recently acquired Skyland Analytics, to share insights on their respective mission to help the biopharma industry reduce the time, cost, and risk of bringing new therapies to market. You'll learn about the market dynamics that led each organization to develop new innovative data management technology and the increasingly important role technology plays in today's disparate manufacturing networks. Christian and Bob will discuss the key factors and expectations of bringing IDBS' Polar and Skyland PIMS solutions together and the ultimate of establishing an end-to-end BioPharma Lifecycle Management (BPLM) offering.



Bob Di ScipioFormer CEO, Skyland Analytics

Bob has spent 25 years serving the life science sector in management and legal roles. Most recently, he served as CEO of Skyland Analytics which developed PIMS™ the first Part 11 compliant, cloud-based application for drug manufacturing data management and supply chain transparency. Prior to Skyland, he served as CEO of Aegis Analytical Corporation (acquired by Dassault Systemes), which developed the BIOVIA Discoverant manufacturing informatics software for the life science sector. Bob has also served in legal and management positions with Martek Biosciences and OmegaTech, and as a tax attorney with PWC.

Christian Marcazzo

General Manager, IDBS

Christian Marcazzo has been the General Manager of IDBS since 2018, leading the business through a period of transition, investment and growth as a Danaher Operating Company. Prior to joining IDBS, Christian has spent 25 years at the interface of biology and software, leading organizations like Perkin Elmer, Spotfire and LION bioscience through the genomics revolution and the digitization of R&D. He has a BA in Molecular and Cell Biology from the University of California, Berkeley and is based at the IDBS headquarters in Surrey, UK.





9.00 AM EDT I 2:00 PM BST | 10:00 AM IST Your journey to the cloud

About the Session:

Struggling with the tools to make the shift to the Cloud? In this session learn from the IDBS experts on how the Cloud-ready organization can leap ahead on their journey to the Cloud. The team will cover the benefits, the experience, and the reality of what a cloud-first system can bring to your organization.

A particular focus will be the IDBS Cloud with a view on some rationale for moving to the Cloud along with the practices IDBS uses in providing Cloud services that pivot customers will experience as part of their migration from their on-premises environments. Use this time to understand how a pivot to the cloud will benefit your organization and ask the tough questions.



Chris OvettSaaS Cloud Product Manager, IDBS

Chris Ovett is the Senior Product Manager for the IDBS Cloud Platform. He is accountable for defining IDBS strategy and executing the roadmap for the underpinning technology and process that enables teams across IDBS to deliver novel products and solutions to our customers. A versatile leader with over twenty years of experience in Product, Solution Architecture, Engineering and Services who places customers at the core, leading them through all stages of their digital journey.

Bharat SwainTechnical Project Manager, GPS, IDBS

Arnaud Muzaton Technical Lead, GPS, IDBS

Angus Tosh SRE Manager, IDBS



10:00 AM EDT I 3:00 PM BST I 11:00 AM IST Best Practices on building and implementing a digital process data strategy

About the Session:

Join this session to hear Skyland PIMS customers sharing their challenges and best practices for capturing, analyzing, reporting, and sharing critical manufacturing process data across internal and external teams, sites and partners. Leaders from bluebird bio, Precision BioSciences, Alnylam Pharmaceuticals and FibroGen will take you through their journey in identifying, implementing, and realizing the value of cloud technology to streamline tech transfer and manufacturing processes, efficiently monitor variability, ensure process control, and secure CMO collaboration and stakeholder buy-in.



Eric Dahlgren
Director of MST, Alnylam

Eric is Director of Manufacturing Technical Services at Alnylam Pharmaceuticals, overseeing starting materials, drug substance, and process analytics for late stage and commercial RNAi programs. In addition to RNAi, Eric's previous experience includes supporting biologics and peptide manufacturing in various roles, including process development and manufacturing technical support. Eric holds a BEng in chemical engineering and mathematics from Vanderbilt University and an MSc in chemical engineering from Worcester Polytechnic Institute.

Matt Wheeler Validation Manager, Precision Biosciences

With 12 years of experience in life sciences, Matt loves having the opportunity to have a positive effect on the fight against disease. He feels energized and privileged to wake up every day and take part in innovative science in the effort to help progress modern medicine. Each day he is supported and surrounded by a group of individuals that are equally driven and passionate about what they do. He explains, "As technology advances into uncharted territory, we collectively find fulfillment in supporting patients and clients with our industry expertise." Matt has served in



roles in microbiology, validation, operations, and most recently data management.





Dr. Rahul Kaushik Senior Vice-President, FibroGen

Dr Rahul Rajan Kaushik is currently at FibroGen, Inc. where he is Senior Vice President, Pharmaceutical Development, Technical and Manufacturing Operations. Prior to this, he was Executive Director and Head of External Manufacturing at Nektar Therapeutics where he led CMC aspects including technology transfer, GMP manufacturing, process characterization, and process validation of Bempegaldesleukin. Rahul spent over 15 years at Amgen, Inc. where he adopted several leadership roles within CMC ranging from formulation development, analytical

development, process development, technology transfer, process characterization, and PPQ oversight. He also established external partnerships for product development and clinical manufacturing, in addition to leading the team that established an end-to-end, state-of-the-art pilot manufacturing facility. Rahul holds an undergraduate degree in Chemistry from I.I.T. Bombay and a Ph.D in Cell Biology from Stanford University.

Margaret Mayo

Process Monitoring Specialist II, bluebird bio

Margaret Mayo is a senior process engineer at bluebird bio. She has established and grown bluebird bio's continued process verification programs at multiple manufacturing partners, helping to realize the vision of commercial gene therapy products. Over the past +6 years, she and her team have made critical contributions toward the pending FDA approval of two of bluebird's products, anticipated this fall. Margaret holds a BS in biomedical engineering from the University of Rochester and has served overseas as a science teacher with the US Peace Corps.





Scott Weiss
VP BD & Innovation, IDBS

Scott Weiss is responsible for developing IDBS' expanding network of technology and channel partners. He joined IDBS in 2004 and has held senior leadership roles in consultancy, product management and strategy. Prior to joining IDBS, Scott spent over 20 years in the pharmaceutical industry, where he led multiple drug-development programs from conceptualization to entry into clinical trials and has authored over 30 peer-reviewed scientific papers and patents. He obtained his PhD in Psychology from the University of Leeds, specializing in Neuroscience.



11:00 AM EDT I 4:00 PM BST | 12:00 PM IST Skyland PIMS Use Case demonstration

About the Session:

Experience first-hand the power and ease of using Skyland PIMS to manage your critical process information and accelerate your product's time to market. During this session, IDBS team members will use real-life examples to demonstrate the value of establishing a centralized, persistent, and dynamic data backbone. See how PIMS easily captures your control strategy and transforms tech transfer for first-time clinical trial runs. Realize how quickly and compliantly PIMS captures batch data across a disparate, global manufacturing network of various IT maturity. And watch how PIMS seamlessly produces outputs to meet your monitoring, investigation, process improvement, and regulatory reporting needs.



Ken Forman PIMS Specialist, IDBS

Ken has over 28 years of experience and expertise in IT, Operations, and Product & Project Management focused in the software and pharmaceutical space. Prior to joining Skyland Analytics, Ken served as Director, Project Management, NAM at BIOVIA Dassault Systemes and held multiple director positions at Aegis Analytical. Previously, he was Director of IT at Rally Software Development, Director of Commercial Operations at Fischer Imaging and Director of IT at Allos Therapeutics and Genomica. In addition to his work accomplishments, he is a Certified Scrum Master. Ken holds a BSc in Computer Science from Cal Poly and an MBA from the University of Colorado, Denver.

David Brick PIMS Specialist, IDBS

David has more than 30 years of experience in consulting, project management, data management and data warehousing for reporting and analytics applications. He has spent more than 20 of these years focused in pharmaceutical and biotech manufacturing and process development. As part of Skyland Analytics and IDBS, David has been responsible for data management, connectivity, and sharing aspects of PIMS as well as technical implementation project delivery. Prior to joining Skyland Analytics, David served as Director, Professional



Services for Dassault Systèmes BIOVIA (and its predecessors Accelrys and Aegis Analytical) where he had responsibility for all implementation activities for Discoverant®, the world's leading informatics software for Life Science manufacturers, and for the Nexus data access and aggregation components of the product. His clients included more than 50 process development and manufacturing facilities worldwide. David has both a BS in Applied Mathematics with University Honors and a MS in Statistics from Carnegie Mellon.





Mallory Turner PIMS Specialist, IDBS

Mallory Turner is a Sr. Manufacturing Intelligence Specialist at IDBS (formerly Skyland Analytics). She has a Masters in Quantitative Research Methods / Research Methods and Statistics from the University of Denver. After graduate school she joined a Colorado startup called Aegis on their analytic consulting team for Discoverant. In her eight years working with various software in bio-pharma manufacturing, she has established customer monitoring systems and company guidelines, delivered best practices training on CPV and Investigations — as well as directly

assisting in numerous customer investigations when an extra set of eyes on an issue was needed. A self-described stats geek, Mallory finds great joy in partnering with a company as they grow from their first control chart to using advance techniques to predict their quality attributes and beyond. For the last two years she has been leading PIMS implementation with customers, strategically advising on product development, and delivering demos to prospective customers.

Sep Mohseni PIMS Specialist, IDBS

Sep Mohseni, Director, West Coast — PIMS, has over 10 years of experience bringing innovative solutions to the Pharmaceutical, Hospital, CDMO/CMO, Medical Device, and Analytical Testing industries. Her expertise in identifying the right IT solutions to address diverse and complex challenges makes her a respected advisor in maximizing value and creating pathways to realize improved service, product quality, and patient safety.

Prior to IDBS, Sep held roles at Spectra and Infinity Laboratories where she aligned with strategic partners and



helped clients define a pathway forward to accelerate product launch and decrease risk in the pharmaceutical and biotech manufacturing process.

12:00 PM EDT I 5:00 PM BST I 1:00 PM IST Closing Note

Christian Marcazzo

General Manager, IDBS

Christian Marcazzo has been the General Manager of IDBS since 2018, leading the business through a period of transition, investment and growth as a Danaher Operating Company. Prior to joining IDBS, Christian has spent 25 years at the interface of biology and software, leading organizations like Perkin Elmer, Spotfire and LION bioscience through the genomics revolution and the digitization of R&D. He has a BA in Molecular and Cell Biology from the University of California, Berkeley and is based at the IDBS headquarters in Surrey, UK.



