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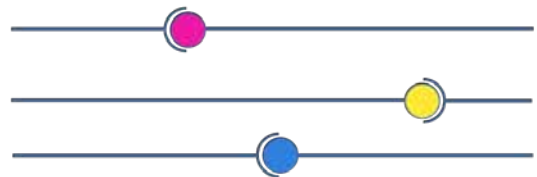
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WELCOME //



WELCOME TO THE 2021 VIRTUAL BIOHIVE SUMMIT //

On behalf of BioUtah and Biohive, we welcome you to the Biohive Summit. This is the 12th year we have gathered the Utah life sciences industry. For the past eleven years you have known the event as the Utah Life Sciences Summit. At our Summit last year we launched our Biohive initiative, an effort to brand, build and bring the industry together. Consistent with that branding effort we have changed the name of the Utah Life Sciences Summit to the Biohive Summit. No other event better symbolizes our desire to brand, build and bring the industry together.

The establishment of our Biohive initiative makes it possible to bring more resources and bandwidth to bear in spreading the good news about the significant life sciences hub Utah is becoming. Leveraging those resources allows us to not only better tell the story, but to positively affect workforce issues, capital raising and industry growth.

The effects of COVID-19 that required we meet virtually in 2020 have again affected our plans for gathering the industry this year. We are meeting virtually, but you will notice a significant upgrade in the presentation. It is just a taste of what we hope will point to an even grander in-person gathering in 2022.

While a virtual format does not allow for gathering in person and the associated networking, it has afforded us the opportunity to attract speakers and Summit participants that may otherwise be unavailable due to travel costs and time commitments.

For instance, we have the privilege this year of hearing from Dr. Dean Li, President of Merck Research Laboratories. Dr. Li is a founder of Recursion Pharma and will have a candid chat with Recursion CEO, Chris Gibson about his view of various industry issues. Kevin Lobo, CEO of Stryker Corporation will be joined by Mark Paul, President of the Salt Lake City based Neurovascular Division of Stryker to explore how patients are the main focus of

developing medical solutions. Doug Cole, Managing Partner of Flagship Pioneering and co-founder or lead investor in numerous therapeutics companies will discuss the future of life sciences. We are also pleased to have Susan Schneider Williams, the widow of actor Robin Williams, speaking about mental health issues and disease.

Our Regulatory, Compliance and Quality track is always a draw. This year should be no different as we host representatives from all three FDA Centers, CDER, CBER and CDRH, who will give a view from the inside of FDA in these challenging COVID times. Other key topics related to MDSAP, IVDR, Brexit and ISO 13485 will also be reviewed by topic experts. The BioUtah track will highlight workforce resources, interviews with Rep. John Curtis and Senator Mitt Romney as well as how to partner with the Department of Defense.

New this year is our Biohive track! This track will feature short, inspirational talks from industry leaders much like a TedTalk. These promise to be thought provoking and insightful. You won't want to miss this session even if you have to watch the recorded version after the Summit.

We express appreciation to all our sponsors who have made this event possible. A special thanks to Renalytix who stepped up again this year as Title Sponsor.

Please enjoy this Summit and look for our follow-up survey so you can provide feedback to help us make future Summits even better.

Kelvyn Cullimore, Jr.
President
BioUtah

Katelin Roberts
Executive Director
Biohive



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BD is a purpose-driven company, *advancing the world of health™* by developing medical devices and sophisticated technologies that doctors, nurses, researchers and caregivers rely on to improve the lives of patients. As partners on the front lines, we've helped the world battle viral diseases for decades, from polio, smallpox and measles to HIV and the annual flu.

Today, the capabilities, expertise and global reach of BD are greater than ever, and in the face of COVID-19, we are mobilizing to equip our healthcare partners with a comprehensive suite of technologies and solutions that are essential to discovering more about the virus, diagnosing patients at scale and supporting patient care.

We're doubling down on what we do best—tapping our deep resources to help solve healthcare's biggest problems, working with urgency to innovate and ensure the front lines have what they need to address this crisis, and making an impact on lives around the world.

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ACCESSING THE WEBINAR //

You may join the webinar via either the desktop or web app.

1. DESKTOP //

Visit biohivesummit.com and click on the “Join Now” button. You’ll need to use the email address you registered with. If you are asked for an event invitation code when accessing the event, use [biohivesummit](https://biohivesummit.com). The webinar platform is most compatible with Google Chrome. You may experience performance issues using any other browser.

2. MOBILE APP //

The Whova mobile app functions as a companion to the desktop version and may be accessed via the App Store or Google Play.

You may also access it at https://whova.com/portal/webapp/rulss_202111/

Once installed, click “Find My Event/Conference” and search for “BioHive Summit.” You’ll then need to login using the email listed on your registration.

VIEWING WEBINAR SESSIONS //

Webinar sessions are viewable in either the desktop version or mobile app via the “Agenda.” You may add sessions you wish to attend to your schedule and view any session in progress. Each session has its own link within the “Agenda.” The live stream of sessions will not be continuous in the same window, so to go from one session to the next, you will need to click on each session in the “Agenda” you wish to view.

SUPPORT //

If you have any problems with your registration or accessing the webinar, please contact BioUtah’s tech support at 801.867.4061 or josel@bioutah.org.

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AGENDA //

OPENING PLENARY SESSION //

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8:30 AM

WELCOME & INDUSTRY UPDATE

KELVYN CULLIMORE, PRESIDENT, BIOUTAH
RANDY RASMUSSEN, CHAIR, BIOUTAH // GOVERNOR SPENCER COX



8:45 AM

FIRESIDE CHAT

CHRIS GIBSON, CEO, RECURSION
DEAN LI, PRESIDENT, MERCK RESEARCH LABS



9:30 AM

PATIENT OUTCOMES: THE BEST RETURN ON INVESTMENT

KEVIN LOBO, CHAIR & CEO, STRYKER
MARK PAUL, PRESIDENT NEUROVASCULAR DIVISION, STRYKER



10:15 AM

BIOLOGY REVOLUTION: THE FUTURE OF LIFE SCIENCES

DR. DOUG COLE, MANAGING PARTNER, FLAGSHIP PIONEERING



10:45 AM

LEWY BODY DEMENTIA: DOES A DIAGNOSIS MATTER?

SUSAN SCHNEIDER WILLIAMS, VICE CHAIR, AMERICAN BRAIN FOUNDATION



11:15 AM

PARITYPLEDGE

CHRIS GIBSON, CEO, RECURSION
JARED BAUER, CEO, CIBUS BIOTECHNOLOGIES AND IONIQ SCIENCES



11:30 AM

AWARDS PRESENTATION

- LIFETIME ACHIEVEMENT // DR. REX SPENDLOVE
- EXECUTIVE OF THE YEAR // SUNNY SANYAL
- ENTREPRENEUR OF THE YEAR // GREG CRITCHFIELD
- INNOVATION IMPACT // CO-DIAGNOSTICS
- FRIEND OF THE INDUSTRY // PIVOT CENTER

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AFTERNOON TRACKS //

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RCQ TRACK //

// **RCQ PLENARY:** CHRIS PHILLIPS, DIR. REG. & CLINICAL AFFAIRS, FLUIDX // HOST

1:00 PM FDA: A VIEW FROM THE INSIDE
DR. CELIA WITTEN, DEPUTY DIRECTOR, CBER
DR. DOUG KELLY, DEPUTY CENTER DIRECTOR FOR SCIENCE, CDRH
DR. JACQUELINE CORRIGAN-CURAY, PRINCIPAL DEPUTY DIRECTOR, CDER

// **DEVICE REGULATORY:** PAUL BROOKS, RETIRED EXECUTIVE DIRECTOR, RAPS // HOST

2:00 PM BREXIT OVER THE POND
TIM LEE, ACCOUNT MANAGER - REGULATORY SERVICES, BSI

2:30 PM MANAGING GLOBAL REQUIREMENTS IN MEDICAL DEVICE DEVELOPMENT
SUSUMU NOZAWA, HEAD OF REG. POLICY, SIEMENS HEALTHINEERS
PETER A. TAKES, PRINCIPAL, REGULATORY INTELLIGENCE ASSOCIATES

// **IVD REGULATORY:** KRISTEN KANACK, SVP, BIOFIRE // HOST

2:00 PM WHAT IS HAPPENING WITH THE IVDR
ANJA WIERSMA, CEO, MI-CE CONSULTANCY
ALEX LAAN, PRINCIPAL CONSULTANT, NAMSA

// **QUALITY:** VICTOR GARCIA, GLOBAL VP REG. AFFAIRS & QA, VAREX IMAGING // HOST

3:00 PM MDSAP LESSONS LEARNED
AUBREY MEACHAM, SENIOR MANAGER QUALITY SYSTEMS, BD

3:30 PM CDRH ALIGNMENT WITH ISO 13485
RAI CHOWDHARY, CEO, THE KPI SYSTEM

AFTERNOON TRACKS //

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BIOUTAH TRACK // KELVYN CULLIMORE, CEO, BIOUTAH // HOST

- 1:00 PM** **UTAH ELEVATED, OPPORTUNITIES IN WORKFORCE DEVELOPMENT**
- JEFF NELSON, CHAIRMAN, NELSON LABS // MODERATOR
 - YVETTE WOODLAND, ECONOMIC SERVICE AREA DIR., DEPARTMENT OF WORKFORCE SERVICES
 - TAMI GOETZ, EXECUTIVE DIRECTOR, STEM ACTION CENTER
 - VIC HOCKETT, DIRECTOR, TALENT READY UTAH
 - JENNI ABBOTT, ASST. V.P. WORKFORCE TRAINING & EDUCATION, SLCC
-

- 2:00 PM** **BEHIND THE SCENES AT CONGRESS**
- REP. JOHN CURTIS, U.S. HOUSE OF REPRESENTATIVES
 - SEN. MITT ROMNEY, U.S. SENATE
-

- 3:00 PM** **DOD: YOUR PARTNER IN FUNDING AND INNOVATION**
- LIZ POWELL, PRESIDENT, G2G CONSULTING // MODERATOR
 - GREG KAPCAR, DIR. OF PUBLIC AFFAIRS, G2G CONSULTING
 - DIANA DEL MONACO, TRAUMA & CLINICAL CARE DIRECTORATE DEPUTY, DEPT. OF DEFENSE
 - AMBER MALLORY, DIRECTOR, TRAUMA & CLINICAL CARE RESEARCH, 59TH MEDICAL WING, OFFICE OF SCIENCE AND TECHNOLOGY

AFTERNOON TRACKS //

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BIOHIVE TRACK // KATELIN ROBERTS, EXECUTIVE DIRECTOR, BIOHIVE // HOST

- 1:00 PM** **KURT WORKMAN**
CEO, OWLET

- 1:15 PM** **CHANDANA HAQUE**
EXECUTIVE DIRECTOR, ALTITUDE LAB

- 1:30 PM** **DAN MCMASTER**
DIRECTOR, STRATEGY & BUS. DEVELOPMENT, 3M HEALTH INFO. SYSTEMS

- 1:45 PM** **KATIE-ROSE SKELLY**
CO-FOUNDER AND CTO, KNOWN MEDICINE

- 2:00 PM** **JAY MUSE**
PRESIDENT & CEO, TALON SURGICAL

- 2:15 PM** **NIC ANDERSON**
HEALTH ECONOMIST, N C ANDERSON CONSULTING

- 2:30 PM** **RYAN WATTS**
CEO, DENALI THERAPEUTICS

- 2:45 PM** **HARRIET HOPF**
PROFESSOR OF ANESTHESIOLOGY, UNIVERSITY OF UTAH

- 3:00 PM** **TINA LARSON**
PRESIDENT & COO, RECURSION

- 3:15 PM** **TROY D'AMBROSIO**
EXECUTIVE DIRECTOR, LASSONDE INSTITUTE, UNIVERSITY OF UTAH



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PARTICIPANTS //



JENNI ABBOTT

ASSISTANT VICE PRESIDENT, WORKFORCE TRAINING & EDUCATION, SALT LAKE COMMUNITY COLLEGE

Jenni Abbott is a higher education administrator experienced in research, labor market data analysis, external funding, and collaboration with industry partners to develop skills-based training for high demand jobs. Her role at SLCC as Assistant Vice President of Workforce Training & Education includes the development of short-term training programs that prepare individuals for high-demand jobs in Salt Lake County. Dr. Abbott received an Ed.D. in Higher Education Leadership from Northcentral University, focused on change management.



JARED BAUER

CEO, CIBUS BIOTECHNOLOGIES AND IONIQ SCIENCES

Jared Bauer is the CEO of both Cibus Biotechnologies Inc. and IONIQ Sciences. Mr. Bauer also serves as the Chairman of the BioUtah SLC Biotech Initiative Advisory Committee where he is leading an effort to brand the Utah Life Science community and expand its global reach, and as a trustee for The Oliver Fund, a non-profit he co-founded. In 2012, Mr. Bauer founded Exuro Medical and acquired BurnFree Products. Jared led the Exuro Medical team to expand BurnFree distribution to 58 countries, making BurnFree the second largest burn treatment product line in the world.



NIC ANDERSON

HEALTH ECONOMIST, N C ANDERSON CONSULTING

Nic is a consultant in health economics, payer perspective, reimbursement and market access. After finishing school in Boston, he began his career as a Payer determining which medical technologies were paid for by Intermountain Healthcare and was a member of Intermountain's New Device and Technology Committee (Value Analysis). He is presently in health economics and market access at a major medical device manufacturer. He is also a forever student of the Austrian School of Economics.



PAUL BROOKS

RETIRED EXECUTIVE DIRECTOR, RAPS

Successful, experienced and recognized as a leader in medical device regulatory affairs, particularly with regard to European medical device regulations, CE Marking and ISO 13485. Provided leadership, vision and management of BSI's Americas Healthcare business and team performance from less than US\$2 million to over US\$50 million, now Americas market leader in services provided. Specialties: Long standing member of RAPS and ASQ Biomedical, highly engaged with the US medical device regulatory environment often presenting and speaking at national and regional events.



RAI CHOWDHARY
CEO, THE KPI SYSTEM

Rai is an entrepreneur, coach, inventor, and author. The KPI System is his eighth startup and is focused on enabling performance improvement with a client list spanning startups to established Fortune 50 companies. Rai has a passion for risk management and believes we are rather naive when it comes to managing risk. His research and work on how we can get ahead in dealing with risk will culminate in his fifth book.



DOUG COLE
MANAGING PARTNER, FLAGSHIP PIONEERING

Doug Cole joined Flagship Pioneering in 2001. He focuses on life science. At Flagship, Doug has co-founded Ensemble Therapeutics, Foghorn Therapeutics, Inzen Therapeutics, Moderna, Permeon Biologics, Sigilon Therapeutics, and Syros Pharmaceuticals. He has led investments in Agios Pharmaceuticals, Alvine Pharmaceuticals, Avedro, CombinatoRx, Concert Pharmaceuticals, Denali Therapeutics, Editas, Qunanterix Corporation, Receptos, Seventh Sense Biosystems, Tetrphase Pharmaceuticals, and Torque. He currently serves on the board of directors of Denali Therapeutics, Cygnal Therapeutics, Foghorn Therapeutics, KSQ Therapeutics, Inzen Therapeutics, Repertoire Immune Medicines, Sana Biotechnology, and Sigilon Therapeutics.





JACQUELINE CORRIGAN-CURAY
PRINCIPAL DEPUTY DIRECTOR, CDER

Jacqueline Corrigan-Curay, J.D., M.D., is the Principal Deputy Center Director in the FDA’s Center for Drug Evaluation and Research (CDER). In that role, she provides executive leadership on strategic initiatives that advance CDER’s mission to deliver safe, effective and high-quality medications to the American public. Dr. Corrigan-Curay previously served as the Director of the Office of Medical Policy in CDER and held leadership positions at the National Institutes of Health.



SPENCER COX
GOVERNOR, STATE OF UTAH

A sixth-generation Utahn, Gov. Spencer J. Cox was born and raised in Fairview, a town of 1,247 residents located about two hours south of Salt Lake City. He graduated from Snow College, Utah State University and Washington and Lee University School of Law. Cox met Abby Palmer at age 16 and they have been smitten with each other ever since. After Spencer’s service as a missionary in Mexico, the couple married and moved away to continue their education. Gov. Cox launched his career as an attorney clerking for U.S. District Judge Ted Stewart and began building a successful law practice at a Salt Lake City firm, Fabian & Clendenin. He returned to Fairview to join the family business, CentraCom, as vice president and general counsel.

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Blog Post

What are the components of a patient monitoring system?



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Intelligent Medical Devices: An Overview





GREG CRITCHFIELD
 CHAIRMAN & CEO, SERA PROGNOSTICS
 AWARDEE //

Greg Critchfield is Chairman & CEO of Sera Prognostics, Inc., a public proteomics diagnostics company with a vision of improving maternal and fetal health through precision pregnancy care. Prior to Sera, he served as President of Myriad Genetic Laboratories where the company grew revenues 54% compounded annually over a 12-year period. He was Chief Medical and Science Officer at Quest Diagnostics, and has served on the boards of ten diagnostics/biopharma/device companies, and worked as an NIH Study Section member and chair reviewing biomedical computing grants over 15-year period.



KELVYN CULLIMORE
 PRESIDENT & CEO, BIOUTAH

Kelvyn has three decades experience as a medtech CEO, over a decade on the board of the Medical Device Manufacturers Association and over a decade as mayor of a suburb of Salt Lake City. He brings a unique understanding of industry and policy issues to advance association objectives and help member companies. He has been CEO of BioUtah since October 2018.



REP. JOHN CURTIS
 REPRESENTATIVE, U.S. HOUSE OF REPRESENTATIVES

John R. Curtis proudly represents Utah's 3rd Congressional District. Since being elected to Congress on November 13, 2017, John has worked on 11 pieces of legislation that were signed into law, ranging in diverse topics such as better managing public lands, combatting human trafficking, supporting small businesses, and more. Additionally, he serves as the inaugural Chairman of the Conservative Climate Caucus and a member of the powerful House Committee on Energy and Commerce. He previously served on the House Natural Resources Committee and Foreign Affairs Committee. The Congressman cares deeply about hearing the diverse perspectives and feedback from his constituents: he held over 100 town halls during his first full year in office. Utah's third district is the youngest in the country, with an average age of 26 years old.

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TROY D’AMBROSIO

EXECUTIVE DIRECTOR, LASSONDE ENTREPRENEUR INSTITUTE

Troy is currently the Executive Director of the Lassonde Entrepreneur Institute at the University of Utah, an Assistant Dean of the David Eccles School of Business and holds a presidential chair in entrepreneurship. Troy is co-founder, officer and director of multiple start-up companies, which attracted over \$700 million in capital; include founding Transworld Telecommunications which was sold to Sprint in 1996, Convergence Communications which was sold to Lockheed Martin in 2005 and Crystal Peak Minerals, Inc., listed on the Toronto Venture Exchange. He has served as the VP of Investor Relations and Corporate Communication for American Stores Company and the Director of Mutual Fund Operations for Wasatch Advisors.



DWIGHT EGAN

CHIEF EXECUTIVE OFFICER, CO-DIAGNOSTICS AWARDEE //

Mr. Egan has been an officer and director since April 2013. Mr. Egan has been engaged in private investment business from February 1999 to the present. He was a senior executive at Data Broadcasting Corporation, a leading provider of wireless, real-time financial market data, news and sophisticated fixed- income portfolio analytics to 27,000 individual and professional investors from 1995 to 1999. He co-founded and served as CEO and Chairman of the Board of Broadcast International, Inc. from 1984 to 1995, when Data Broadcasting Corporation acquired Broadcast International and created CBS MarketWatch, a leading financial news site and participated in its initial public offering.



DIANA DEL MONACO

TRAUMA & CLINICAL CARE DIRECTORATE DEPUTY, DEPARTMENT OF DEFENSE

Dr. del Monaco currently serves as the Trauma and Clinical Care directorate deputy and Sr. Scientist responsible for conducting, coordinating, and assisting in combat casualty/ austere care research to include evaluating and improving currently available therapies and clinical practice guidelines with the goal of returning wounded warriors to full function. She is a designated 59MDW Institutional HRPO reviewer helping to support external research activity and has over 15 years of human subjects’ protection and regulatory experience.



Congratulations to BioUtah for a successful BioHive Summit!

BIO is honored to partner with BioUtah to support Utah’s thriving biotechnology sector.





VICTOR H. GARCIA

GLOBAL VP REG. AFFAIRS & QA, VAREX IMAGING CORPORATION

Victor Garcia is the Vice President of Regulatory and Quality Compliance for Varex Imaging, overseeing all regulatory, environmental and quality processes as a manufacturer of life saving products. Victor held many senior leadership and advisory positions with companies in highly-regulated environments. He has over 25 years experience in life sciences and helped companies achieve full product approvals, clearances across domestic and international markets. Victor received degrees in biological sciences and molecular biology from University of Mary Washington and California State University, respectively.



CHRIS GIBSON

CEO, RECURSION

Chris Gibson, Ph.D., is the Co-Founder and CEO of Recursion Pharmaceuticals, a clinical-stage biopharma company leveraging the latest in automation, artificial intelligence, biology and chemistry to discover new medicines at scale. Chris is a graduate of Rice University with degrees in bioengineering and managerial studies, as well as a Ph.D. from the University of Utah training with Recursion co-founder Dean Y. Li, MD/PhD. Chris is a Board Member of CureHHT, a patient advocacy group for Hereditary Hemorrhagic Telangiectasia, and a member of the Rare and Undiagnosed Network Advisory Board. Outside of work, Chris enjoys cycling on both the road and the trails that cut through Utah’s great wilderness, as well as spending time with family.

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TAMI GOETZ

EXECUTIVE DIRECTOR, STEM ACTION CENTER

Dr. Goetz is the Director for the Utah STEM Action Center and prior to this she was the Governor’s Science Advisor. Tamara helped to design and implement programs in STEM education and received the “40 Under 40 Rising Stars”, “30 Women to Watch” by Utah Business magazine, the Award of Merit by the National Association for Career and Technical Education, the Women’s Technology Council’s “Community Builder” award and Governor’s Medal for Science and Technology.



CHANDANA HAQUE

EXECUTIVE DIRECTOR, ALTITUDE LAB

Chandana Haque is a product strategist with over a decade of experience operating life science startups. Chandana earned her B.S. at Carnegie Mellon and her MBA from UC Berkeley—Haas School of Business where she focused her graduate work in strategic finance and innovation. While earning her degree, she worked in venture capital and researched novel approaches to innovation. Chandana has developed a passion for coaching founders and an appreciation for the systemic challenges underrepresented founders face.





VIC HOCKETT

DIRECTOR, TALENT READY UTAH

As director of Talent Ready Utah, Hockett oversees the state's public-private partnerships between industry and education in order to support and grow Utah's workforce and talent pipeline. Hockett has over 13 years of operations and executive leadership experience in the advanced manufacturing sector and more than 8 years of experience in higher education, including 5 years of service as the Vice President of Operations at Dixie Tech College.



HARRIET HOPF

PROFESSOR OF ANESTHESIOLOGY, UNIVERSITY OF UTAH

Harriet W. Hopf, MD, is Professor of Anesthesiology, Adjunct Professor of Biomedical Engineering, and Co-Director of the Utah Coaching and Advancement Network (U-CAN) at the University of Utah. She is immediate past Board Chair for the Foundation for Anesthesia Education and Research (FAER). Her research focuses on preventing healthcare associated infections, reducing environmental impact of healthcare, gender equity, and professionalism. In 2020, she was selected to be part of the Utah Women 2020 Mural (<http://womensmural.com/>).

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KRISTEN KANACK

SVP, BIOFIRE DIAGNOSTICS/BIOMERIEUX

Dr. Kanack holds Bachelor of Science, Master of Science, and PhD degrees in Medical/Molecular Microbiology. She has more than 20 years of experience in Microbiology and more than 13 years of experience in the development lifecycle of IVDs for infectious disease. She currently leads R&D and Programs for BioFire Diagnostics/bioMérieux, which spans the global development, validation, registration, and postmarket surveillance of the BioFire product line of user-friendly syndromic sample-to-answer PCR-based diagnostic panels.



GREG KAPCAR

DIR. OF PUBLIC AFFAIRS, G2G CONSULTING

Greg Kapcar leads G2G Consulting’s non-dilutive funding grant tracking team, producing a comprehensive monthly report of funding opportunities for bioscience and high-tech companies. Before joining G2G, Greg founded a government affairs program at a large health and human services non-profit, successfully securing government and foundation funding. He has served as Legislative Director at a statewide trade association where he led efforts to advance health related policy changes and government funding requests.



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DOUG KELLY

DEPUTY CENTER DIRECTOR FOR SCIENCE AND CHIEF SCIENTIST , CDRH

Doug Kelly, MD became Deputy Director and Chief Scientist at the FDA’s device, diagnostics and digital health branch in 2020 after a 30-year seed and early-stage life sciences venture capital career starting, financing, growing and exiting companies spanning biotech, medical devices, robotics, laboratory tools, healthcare IT, ADME/Tox simulation and clinical trial software. At CDRH, Doug is the interface between the FDA and patient and physician groups, payors, industry, academia, innovators, investors, and other agencies and governments.



ALEX LAAN

PRINCIPAL REGULATORY CONSULTANT, NAMSA

Twelve years Notified Body experience, Former Principal Certification Manager at DEKRA Certification BV, Notified Body for IVD and Medical devices at Arnhem. Experienced in liaising with other European Notified Bodies as an active member of IVD working groups. Served as technical file assessor and lead auditor for various IVDs and Medical devices at DEKRA. Served as a product specialist for immuno-hematological and plasma products with Sanquin Blood Transfusion Services. Held roles of QA and RA Manager within IVD companies and experienced with CE marking, device registrations and QMS compliance.



TINA LARSON

PRESIDENT & COO, RECURSION

Tina Marriott Larson joined Recursion as chief operating officer in July 2018 and president in October 2019. She began her career at Genetech/Roche, where she spent 20 years and eventually served on the executive team at Achaogen. Larson has been recognized as a Healthcare Business Women’s Association Rising Star (2012), Utah Business Magazine as CXO of the Year (2020), and is a Women Tech Council Awards winner (2019).



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TIM LEE

ACCOUNT MANAGER - REGULATORY SERVICES, BSI

Tim has been in the medical devices industry for over seven years, working for BSI for the last five. In his current role, Tim helps medical device and IVD manufacturers understand the international regulatory requirements to sell into global markets (ISO 13485, MDSAP, CE Marking, etc). Tim covers the Northwest of the U.S. and is a technical reviewer of all MDSAP applications submitted in America.



DEAN LI

PRESIDENT, MERCK RESEARCH LABS

Dean Li, MD, PhD is President of Merck Research Laboratories. Prior to joining Merck in March of 2017, Dean served as the Chief Scientific Officer, Associate Vice President and Vice Dean at the University of Utah Health System, and interim CEO of ARUP Laboratories, a major national reference laboratory wholly owned by the University of Utah. During his almost 25-year tenure at the University of Utah his academic investigations nucleated three biotechnology companies (Hydra Biosciences, Navigen Pharmaceuticals, Recursion Pharmaceuticals). Dean served as the founding CSO for each of these companies. Dean received his undergraduate degree in Chemistry from the University of Chicago, and his MD/ PhD degrees and internal medicine residency/cardiology fellowship at Washington University School of Medicine in St. Louis.



KEVIN LOBO

CHAIR & CEO, STRYKER

Kevin A. Lobo has been CEO of Stryker since October 1, 2012, and also assumed the role of Chair of the Board on July 22, 2014. He serves on the board of directors for Parker Hannifin, AdvaMed, and the U.S.-India Business Council. He has a broad business career across multiple industries, including finance positions with KPMG, Unilever, and Kraft Canada; roles at Rhone-Poulenc in Europe; and President of Ethicon Endo Surgery at Johnson & Johnson.





AMBER MALLORY

**DIRECTOR, TRAUMA & CLINICAL CARE RESEARCH
59TH MEDICAL WING, OFFICE OF SCIENCE AND
TECHNOLOGY**

Dr. Amber Mallory joined the DoD research ranks in 2013, first as a research toxicologist, and then became Director of Combat Casualty Care and Operational Medicine at Naval Medical Research Unit San Antonio in 2015, where she oversaw a diverse portfolio of projects ranging from expeditionary and trauma medicine and cellular and immune-based adjuncts for casualty care to hemostatic medical devices and medical effects of directed energy insults. She has extensive experience with IACUC and designing in vivo research protocols. Dr Mallory moved to the Air Force as Director for Trauma and Clinical Care Research with the 59MDW Science and Technology Office in April, 2018.



KEITH MARMER

**CHIEF INNOVATION & ECONOMIC ENGAGEMENT
OFFICER, PIVOT CENTER
AWARDEE //**

Keith Marmar is the Chief Innovation & Economic Engagement Officer at the University of Utah PIVOT Center. The PIVOT Center serves as a catalyst for the regional innovation economy - integrating technology commercialization, corporate engagement, and economic development. PIVOT connects the life sciences industry with the U's talent, innovation, and resources; attracts investment; and helps develop technologies and companies. More than 330 companies have spun out from the U, including BioFire, Myriad, and Recursion.

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DAN MCMASTER

DIRECTOR, STRATEGY & BUS. DEVELOPMENT, 3M HEALTH INFO. SYSTEMS

Dan is the chief strategy officer for 3M HISD, the fastest growing division of 3M Company, headquartered in Utah. Dan led the \$1B acquisition of M*Modal, has served as a board advisor to several successful health care companies, and has held numerous leadership positions building growth businesses over his career. Dan lives in Millcreek, UT with his wife and children, where he volunteers locally in church, community, and health care organizations, and enjoys the outdoors.



AUBREY MEACHAM

SENIOR MANAGER, QUALITY SYSTEMS, BD

Aubrey Meacham has supported QMS compliance for over ten years. She has extensive experience managing a variety of device and drug manufacturing audits. She successfully led the effort to prepare for and manage initial MDSAP certification audits at two different sites and has subsequently managed multiple MDSAP surveillance audits.



JAY MUSE

PRESIDENT & CEO, TALON SURGICAL

Jay is an Operating Partner with the Med Venture Holdings group. He is currently President and CEO of Piper Access, LLC, a vascular access company and Talon Medical, LLC (DBA Talon Surgical), a heart access company. He has 27 years of experience in innovation, engineering, technology development, and commercialization. Jay is passionate about developing medical devices that are loved by both clinicians and patients. Prior to the Piper Access and Talon Surgical, Jay worked for GE, IOMEGA, BD, & BARD in the management of product innovation & technology development. He currently resides in Salt Lake City, UT where he enjoys backcountry skiing and mountain biking.

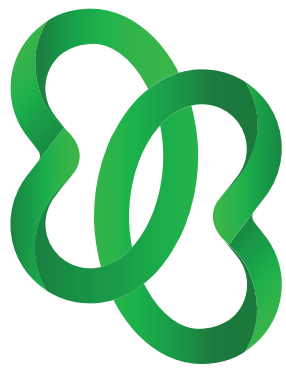


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JEFF NELSON
CHAIRMAN, NELSON LABS

Jeffery R. Nelson is a passionate leader who has dedicated his career to improving the quality of life for people around the world by helping ensure that medical products adhere to the highest quality standards. As Chairman of Nelson Laboratories, he used his unique blended background in business acumen and microbiology expertise to help the company become a global leader in providing microbiology, chemistry, and expert advisory services.



SUSUMU NOZAWA
HEAD OF REG. POLICY, SIEMENS HEALTHINEERS

Susumu is Head of Regulatory Policy for North America at Siemens Healthineers in Malvern, PA. He is responsible for proactively monitor relevant Technical Regulations and Standards to sense critical regulatory policy changes and opportunities, communicate and coordinate all stakeholders to realize favorable regulatory/business environment for Siemens Healthineers, Industry, and the patients Siemens Healthineers serves. Susumu has more than 30 years experience in the medical device industry and held various positions in R&D, Regulatory Affairs and Compliance, and Quality Assurance for global operation. He currently serves as a Vice Chair of Standards Committees at Medical Imaging Technology Alliance (MITA), and actively participates in working groups and technical committees.

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MARK PAUL

PRESIDENT NEUROVASCULAR DIVISION, STRYKER

Mark H. Paul is President of the Neurovascular division at Stryker. Stryker Neurovascular is a pioneer in the development of technologies for the treatment of Hemorrhagic and Ischemic Stroke. For the past 14 years Mark has led one of the largest neurosurgery organizations in the world resulting in significant revenue growth and team skillset expansion. Mark has full P&L responsibilities for all operational functions internally along with sales and marketing teams in +60 countries around the world. Mark is a ~30-year veteran of the Less Invasive Medical Device industry.



CHRISTOPHER PHILLIPS

DIR. REG. & CLINICAL AFFAIRS, FLUIDX MEDICAL

Chris is a recognized leader with extensive experience in Medical Device Regulatory Affairs, Clinical Affairs, and Quality Assurance. Chris has brought innovative medical devices to market in the USA, Europe, and other markets for large and small companies. Chris currently leads Fluidx Medical’s regulatory and clinical efforts, navigating the intersection of these two critical areas. Chris completed a Master of Science degree in Regulatory Affairs and holds RAPS’ RAC (US) and ASQ’s CBA certifications. Chris is currently serving as Chair of BioUtah’s RCQ Committee.

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- Ryan Watts, Ph.D., Denali Chief Executive Officer



denalitherapeutics.com



LIZ POWELL

FOUNDER & PRESIDENT, G2G CONSULTING

Liz is originally from the Boston, MA area and has over two decades of experience from working on health, defense, high-tech and economic development issues in Congress and as an attorney and lobbyist. She started G2G in 2007 and manages government relationships and operations in our Washington, D.C. and Ohio offices. Previously, Liz served as the Legislative Director for Congressman Jim Langevin (RI) and Congresswoman Juanita Millender-McDonald (CA) in Washington, D.C., campaign staff for Congressional and presidential campaigns, Public Affairs Manager and lobbyist for a national association called NAADAC, the President of a women’s networking organization called WIN, and the Policy Analyst for the UK Parliament on the Health Committee.



RANDY RASMUSSEN

CHAIR, BIOUTAH

Dr. Rasmussen co-founded BioFire Diagnostics (then Idaho Technology) in 1990. He served as Chief Operating Officer from 1999 to 2008 and President from 2008 to 2014. Dr. Rasmussen became Chief Executive Officer of BioFire Diagnostics after the acquisition of BioFire by BioMérieux in January of 2014. Dr. Rasmussen was previously with ARUP Laboratories as Medical Director from 1996 to 1999. He also held positions at the University of Utah Cardiology Department and Cardiovascular Pharmacology and Engineering Consultants. Dr. Rasmussen is an inventor on over 20 patents in the fields of real-time PCR, sample-to-answer molecular diagnostics and syndromic testing for infectious diseases. Dr. Rasmussen has a Ph.D. in Biology from the University of Utah and a B.S in Biochemistry from Utah State University.



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KATELIN ROBERTS
EXECUTIVE DIRECTOR, BIOHIVE

Katelin has management and operations experience within various industries including; aerospace, food manufacturing, and technology. Although Katelin has managed large corporate departments with 130+ people and \$86M annually, her passion lies in contributing to the growth and success of small companies that aspire to affect change in the world and improve patient healthcare. In her downtime, you can find Katelin spending time with her family or fly fishing on local waters.



MITT ROMNEY
SENATOR, U.S. SENATE

Senator Mitt Romney was sworn in as Utah's newest senator on January 3, 2019. He currently serves on the Foreign Relations; Health, Education, Labor & Pensions; Homeland Security & Government Affairs; and Budget committees. On the Foreign Relations Committee, Senator Romney serves as Ranking Member of the Subcommittee on East Asia, the Pacific, and International Cybersecurity Policy. He is also a member of the Senate National Security Working Group. Before entering public service, he led a successful business career as the co-founder of Bain Capital, a leading investment company, and the turnaround CEO of Bain & Company, an international management consulting firm. Prior to serving as the Governor of Massachusetts from 2003 to 2007, Senator Romney led the 2002 Salt Lake Organizing Committee for the Winter Olympics and, with a team of volunteers and managers, helped turn the struggling Games into a Utah success story. He was a candidate for the 2008 Republican presidential nomination and Republican nominee for president in 2012.



SUSAN SCHNEIDER WILLIAMS
VICE CHAIR, AMERICAN BRAIN FOUNDATION

In 2014, when her husband Robin Williams died from Lewy body disease (LBD), artist Susan Schneider Williams set out to raise awareness about this devastating yet little known brain disease. Since receiving her husband's diagnosis after his death, only apparent in autopsy, she has become a prominent advocate and voice for LBD and brain disease research. Susan has served on the board at the American Brain Foundation (ABF) since 2016 and spearheaded the ABF's groundbreaking 2021 research award targeted at the discovery of an accurate method of diagnosing Lewy body dementia. Susan participated in the 2020 released documentary film *Robin's Wish*, centered around Robin's final years and his experience with LBD. She authored the editorial "The terrorist inside my husband's brain," for the American Academy of Neurology's *Neurology Journal* and has lobbied in Washington, DC for better diagnostics, increased funding, and support for researchers, doctors and clinicians. Susan has become a leading spokesperson for Lewy body dementia appearing on national television including, *The Today Show*, *Good Morning America* and *CBS This Morning*. Alongside her fine art career, Susan continues her advocacy work to help bridge understanding about this disease where she can.

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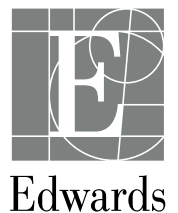


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KATIE-ROSE SKELLY

CO-FOUNDER AND CTO, KNOWN MEDICINE

Katie-Rose is a co-founder and Chief Technology Officer at Known Medicine. Her career has focused around the application of AI and data science to biology. She spent several years as a data scientist identifying novel ways of determining drug efficacy at Recursion Pharmaceuticals. She received her MS in Biomedical Informatics and BS in Computer Science from Stanford University.



REX SPENDLOVE

FOUNDER, HYCLONE LABS

AWARDEE //

In 1970, Rex founded HyClone Laboratories, shortly after joining Utah State University as Dept head of Microbiology. Due to the poor quality of commercially available serum, Rex began collecting blood from local meat packing plants to process his own serum. HyClone has become a worldwide brand with sales exceeding \$1 billion in Logan. Rex directed HyClone until he sold the company in 1996. Since then, Rex has founded Quansys Biosciences, studies Alzheimer's disease, air quality, and the origin of life.



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SUNNY SUNYAL

PRESIDENT AND CEO, VAREX IMAGING

AWARDEE //

Sunny Sunyal serves as CEO of Varex Imaging Corp (Nasdaq: VREX) which spun out of Varian Medical Systems in 2017. Varex is a global market leader in the field of x-ray based imaging. Sunny has over 30 years' experience in various medical technology and healthcare services field. Prior to Varex/Varian, Sunny held senior executive positions at T-System, GE Healthcare, and McKesson. He received a masters in business administration from Harvard University.



RYAN WATTS

CEO, DENALI THERAPEUTICS

Ryan Watts is the Chief Executive Officer of Denali Therapeutics. He is a cofounder, President and a member of the Board of Directors. Under Watts' leadership, Denali has advanced multiple therapeutic candidates into clinical testing for Parkinson's disease, Alzheimer's disease, and ALS. Denali has invented a proprietary blood-brain barrier platform for delivery of therapeutic proteins to the brain. Watts has also led efforts to raise significant capital to advance Denali's therapeutic pipeline and has been instrumental in forging partnerships to accelerate the discovery and development of medicines for neurodegeneration. Watts previously served as Director of the Department of Neuroscience at Genentech. During his tenure there, he led the company's re-entry into neuroscience.



PETER A. TAKES

PRINCIPAL, REGULATORY INTELLIGENCE ASSOCIATES

Peter A. Takes, Ph.D., RAC, FRAPS, is Principal with Regulatory Intelligence Associates, Director of the MS in Science Management & Leadership Program at Webster University, and has appointments at Washington University School of Medicine, and St. Louis Community College. He holds a Ph.D. in Immunology and has served in various corporate executive and scientific positions in regulatory affairs and compliance, has over 30 books and publications, and is Lead Medical Device Section Editor for RAPS.



ANJA PHD WIERSMA

CEO, MI-CE CONSULTANCY

Anja Wiersma, is a medical biologist by training with a PhD. After working for 8 years at a multinational Pharmaceutical company (Organon), she started to work for a Notified Body in the field of Medical Devices and In Vitro Diagnostic Medical Devices. She was working for this notified body for 6.5 years. She is fully qualified as a notified body auditor for both the MDD (93/42/EEC); MDR (EU 2017/745) and the IVDD (98/79/EC) and IVDR (EU 2017/746). Since 2010 she is a RA/QA consultant for medical device and in vitro diagnostic device manufacturers, and she remains a contractor for several notified bodies executing file reviews and CE and ISO 13485 audits. As of Jan 2013 until Aug 2015 she was a part time QA/RA director and member of management team of an IVD company in the Netherlands.



CELIA M. WITTEN
DEPUTY DIRECTOR, CBER

Celia M. Witten, Ph.D., M. D. is the Deputy Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration (FDA/CBER). Between 2005 and 2016 she served as the Director of the Office of Cellular, Tissue and Gene Therapy at the FDA/CBER. Between 1996 and 2005 she served as Director of the Division of General, Restorative, and Neurological Devices in the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH). Previous to FDA, she worked for over 10 years as a practicing physician at the National Rehabilitation Hospital (NRH) in Washington, D.C. Her educational background includes a B.A. earned at Princeton University (Magna Cum Laude), a Ph.D. from Stanford University, and an M.D. from the University of Miami School of Medicine.




KURT WORKMAN
CEO, OWLET

Kurt Workman is the CEO and co-founder of Owlet Baby Care. He has dedicated the last decade to revolutionizing infant health, leading Owlet’s growth from its inception and overseeing research and development of the company’s pipeline, including its connected nursery ecosystem of products. He has also served as a member of Owlet’s board of directors since he co-founded the company, and continues to provide key oversight of Owlet’s product portfolio and growth opportunities.



YVETTE WOODLAND
ECONOMIC SERVICE AREA DIR., DEPARTMENT OF
WORKFORCE SERVICES

Yvette Woodland is an assistant director in the Utah Department of Workforce Services’ Workforce Development Division. An energetic and well-rounded public servant, she enjoys being part of an organization dedicated to strengthening families and communities through partnerships. A lifelong resident of Utah and University of Utah graduate, Yvette lives in Davis County with her family. She appreciates a good book, enjoys a long hike, and adores her children and grandchildren.



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**Contact Danny Woodbury
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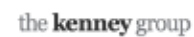
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