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Unprecedented Expertise in Manufacturing and Development for the Cell Therapy Industry

Team Member Biographies

Hitachi Chemical Advanced Therapeutics Solutions, LLC

“The key to our success is grounded in the talents of our superior team.”

- **Robert A Preti, PhD, CEO and President**

Enterprise and Business Leaders

Robert A. Preti, PhD

General Manager, Hitachi Chemical Regenerative Medicine Business Sector; CEO & President, Hitachi Chemical Advanced Therapeutics Solutions (HCATS)

PhD with distinction (biology) New York University

Robert (Bob) Preti is HCATS's co-founder and the visionary behind its successful growth and development strategy over much of the last two decades. Bob built HCATS to meet a recognized need for high quality manufacturing and development services in an emerging industry. As the cell therapy field has grown, so too has HCATS – the company has now served over 100 Clients and performed more than 30,000 cell therapy procedures. Bob's leadership has been instrumental in creating HCATS's Client-focused model that helps bridge the gap between discovery and patient care through eff icient transfer of cell-based therapies from laboratory into clinical practice. His vision for HCATS includes expansion of its manufacturing capacity in the U.S. and Europe, as well as the development of new technological and engineering innovations that will help streamline and automate many cell processing techniques, leading to faster scale up, lower cost of goods, and improved robustness for the industry.

Before assuming his role at HCATS, Bob held a number of positions within the cellular therapy and blood banking fields. From 1996 to 1999, he was the director of hematopoietic stem cell processing and applied research at Hackensack University Medical Center in Hackensack, N.J. He served in several capacities with the New York Blood Center from 1990 to 1997, including tissue bank director, director of hematopoietic stem cell processing, scientific director and associate investigator. He also worked as a research scientist for Marrow-Tech Incorporated, which went on to become Advanced Tissue Sciences (ATIS), where work in his laboratory lead to the Dermagraft product currently marketed by Shire Regenerative Medicine.

Bob began his career in academics, teaching first as an elementary and secondary level educator, then as an adjunct assistant professor and lecturer at Hunter College, an assistant professor at Queensborough Community College, and then adjunct assistant professor at York College. He also has served as clinical assistant professor of medicine for New York Medical College in Valhalla, N.Y.

Robert A. Preti, PhD

General Manager, Hitachi Chemical Regenerative Medicine Business Sector; CEO & President, Hitachi Chemical Advanced Therapeutics Solutions (HCATS)

PhD with distinction (biology) New York University

(continued) Also active in the public health arena, Bob has served on the Stem Cell Banking Committee and Cord Blood Subcommittee of the New York State Department of Health and on the New Jersey State Department of Health's Blood Bank Advisory Committee, chairing the Hematopoietic Progenitor Cell Processing Subcommittee.

In addition, he has served in a leadership capacity for many professional organizations, including treasurer and founding member of the International Society of Hematotherapy and Graft Engineering, now called ISCT (International Society for Cellular Therapy). He has published and presented extensively on a variety of topics relating to cellular therapies. He recently completed a five year term as a director for AABB, and is currently Chairman for the Alliance for Regenerative Medicine (ARM), where, among other activities, he chairs the Strategic Planning Committee.

Announced on June 27, 2016, Bob was made Chairman of the Alliance for Regenerative Medicine (ARM), the preeminent global advocate for regenerative and advanced therapies. By leveraging the expertise of its membership, ARM empowers multiple stakeholders to promote legislative, regulatory and public understanding of, and support for, this expanding field.

Sanjin Zvonic, PhD

Senior Director, Business Leader, Clinical and Commercial Manufacturing

PhD (cell and molecular biology) Louisiana State University

Sanjin joined HCATS in April 2016 as Senior Director, Business Leader, Clinical and Commercial Manufacturing. In this role, Sanjin is responsible for driving the creation and implementation of business strategies to delivas means of driving manufacturing business units' growth, profitability and competitive advantage.

Prior to joining HCATS, Sanjin worked at Novartis as Senior Fellow, Technical Research & Development, Cell & Gene Therapy Unit, where he was responsible for various elements of the clincal, process and product development of 2 late-stage pipeline products, in preparation for commercialization, including the recently FDA-approved Kymirah.

Before his experience at Novartis, Sanjin initially worked at PCT from 2009 to 2014 as Director, Technology & Business Development, then from January to July, 2014 as Director, Technology Applications. In this role, Sanjin was responsible for driving the creation of client-specific service platforms designed to address each client's unique needs and enable their long-term success. He also worked with project managers on technology transfer and performed regulatory and consulting services for clients.

Sanjin's previous roles include Industrial Liaison/Process Development Director, Tulane University Center for Gene Therapy and Senior Postdoctoral Fellow/QC Associate, Tulane University Center for Gene Therapy.

Sanjin is the author of more than 20 peer-reviewed articles published in top-tier academic journals, serves as an ad-hoc reviewer on four cell biology journals, and has given more than 30 talks and presentations at both academic and industry events.

Thomas Heathman, PhD

Business Leader, Technology Development, Manufacturing Development & GTP Services

PhD, Regenerative Medicine, Loughborough University, UK

Tom joined HCATS in November 2015 as a Business Development Associate and currently acts as the Business Leader in Technology and Product Development. In this role, Tom is responsible for clients' customer experience as well as the growth, profitability and operational excellence of the technology and product development business line.

Tom's PhD focused on developing process control strategies for the large-scale manufacture of human mesenchymal stem cells in bioreactors. During his PhD program, Tom was actively involved in business development activities which included leading multiple contract research projects with industry partners, facilitating collaborative projects in regenerative medicine between the UK and Japan, and enabling collaborative presentations and publications. Tom has a Master's degree in Chemical Engineering from the University of Bath, UK and previously worked as an intern Process Engineer at the BP Research and Technology Centre in the UK where he was responsible for driving the implementation of two key pilot plant projects, leading teams of process specialists to successfully deliver these projects, on time and on budget.

Tom has received a number of prestigious awards in the field, authored multiple original research publications and book chapters on the subject of cell therapy manufacture, and holds a number of committee positions in regenerative medicine.

Manufacturing Operations

William J. Monteith

Chief Operating Officer

B.S. (chemistry) Saint Lawrence University

William Monteith joined HCATS in October, 2015. He is a dynamic global pharmaceutical operations and quality executive with a documented record of organizational success and a proven record of accomplishment in strategic planning and execution, business process improvement, cost reduction, FDA and DEA regulatory compliance, facility startup and turnaround, technical transfer and analytical method validation, supply chain, and multi-plant management.

Before joining HCATS, William was VP and General Manager, and then Executive VP, Technical Operations, at immunotherapy biotechnology company Dendreon Corporation. He has also held leadership roles at Sandoz, Shire, and Wyeth pharmaceuticals, ranging from technical operations to quality assurance.

William is a member of the American Chemical Society, the American Society of Quality Professionals, the American Society of Pharmaceutical Scientists, and the International Society of Pharmaceutical Engineers.

Andrew Fitzpatrick

Senior Director, Manufacturing
Allendale, NJ

BS (biology) Montclair State University

Andrew joined HCATS on September 12, 2016. As Senior Site Director at the Allendale facility, Andrew is responsible for all manufacturing activities at the site. Andrew comes to HCATS with extensive experience in GMP aseptic manufacturing (cellular therapies, biopharmaceuticals, and medical devices), quality assurance, and validation. Prior to his role at HCATS, Andrew was Director of Manufacturing for Cresilon and Director of Manufacturing Operations for Celgene Cellular Therapeutics (CCT), among other roles at CCT and Roche. Andrew's strengths include, team building and leadership, cGMP manufacturing facility design and start-up, and quality systems implementation.

Jesse Ayala

Senior Site Director
Mountain View, CA

BS (biology) California State University-Hayward

Jesus (Jesse) Ayala joined HCATS in January 2016. As Senior Site Director at the Mountain View facility, Jesse is responsible for global process and assay development activities. Jesse brings to his role at HCATS proven hands-on experience in the manufacturing of medical devices, bio-pharma and biotechnology products and an exceptional understanding of aseptic process and cleanroom behavior, equipment, personnel development, management and regulations.

Prior to his role at HCATS, Jesse served as Senior Director of Drug Products for Therapeutic Proteins International, Director of Manufacturing for Dendreon and Business Development Manager for MicroBiology & Quality Associates, among other roles.

Jesse's specialties include managing cGMP facilities with cleanroom areas, training and development of aseptic process personnel, team building and mentoring, developing manufacturing policies and programs, and lean manufacturing and QbD knowledge.

Saulye Sherrell

Director, Manufacturing Operations
Mountain View, CA

MS (molecular genetics) Kazakh National University

Saulye Sherrell joined HCATS in November 2016. As Director, Manufacturing Operations, Saulye will be responsible for the daily manufacturing operations at the Mountain View site.

Saulye has a background in biotech manufacturing and process excellence. Prior to joining HCATS, Saulye held multiple management positions in manufacturing at Bayer Corporation, most recently as Associate Director, API Cell Culture/Isolation. Prior to that, she was Operational Excellence Manager with Genentech.

Saulye holds many professional certifications that, along with her extensive experience, make her an asset to HCATS, including a Lean BioPharma Certificate from the University of Michigan, Lean Certification from Lean Enterprise and a Process Master Certificate from Michael Hammer Co.

Mark Johnson

Director, Engineering

B.S. (mechanical engineering) Clarkson College of Technology

Mark Johnson joined HCATS in February 2016. Throughout his career, Mark has had extensive biotech facility design, construction, and startup project team leadership experience.

He also has extensive facilities/maintenance experience, including facilities management, metrology, preventive and predictive maintenance, plant engineering, personnel administration, computerized maintenance management, control and monitoring systems, contractor and service provider management. Before joining HCATS, Mark served as Director of Engineering at Dendreon, the first biotechnology company with an approved commercial immunotherapy product. At Dendreon, Mark was actively engaged in supporting commercial operations, as well as engineering/facility responsibilities. Mark also was Facility Project Manager at Osteotech, and Project Manager, Capital Projects at Wyeth, among other positions.

Mark has a solid background in biotech and vaccine processes, cleanroom design and operation, cGMP and EMA requirements, and facility and equipment commissioning/validation. He is fluent in English and Portuguese.

Scott Oppenheim

Director, Supply Chain

PhD with distinction (biology) New York University

Scott Oppenheim joined HCATS in April 2016 as Director, Supply Chain. He is responsible for the development of corporate-wide inventory and materials management controls and policies. Scott also oversees the scheduling system for manufacture at all sites as well as the planning and purchasing of materials. Scott has direct line responsibility for the Allendale and Mountain View warehousing, materials management and regenerative cell storage areas.

Prior to joining HCATS, Scott worked at Novartis as member of the Cell & Gene Therapy Unit, where he was responsible for multiple elements of the Supply Chain in preparation for commercialization. This included involvement with the recently FDA-approved Kymirah. Scott also served as Supply Chain Manager at Dendreon, the first biotechnology company with an approved commercial immunotherapy product

Scott brings 26 years of Supply Chain experience including Scheduling. Planning, Inventory Control, Shipping/Receiving and ERP implementation and optimization to HCATS. He has developed inventory, planning and scheduling systems at SPX Precision Components, Dendreon and most recently Novartis. Scott is also APICS certified in Production and Inventory Management (CPIM).

Quality

George Bitar

Executive Director, Quality Operations

M.S (Chemistry and Pharmaceutical Business Management), Seton Hall University

George Bitar joined HCATS in July 2017 as Executive Director, Quality Operations. George comes to HCATS from Pfizer. For the past four years, George has worked at InnoPharma (which was acquired by Pfizer) in the role of Sr. Director and Vice President of Quality. Previous to that he was Sr. Manager of Compliance for Discovery Laboratories and Sr. Sterile Manufacturing Team Leader at Roche Pharmaceuticals. In these roles, George was responsible for developing and implementing Quality Systems to enhance the state of cGMP and to prepare the sites for commercialization of their clinical sterile products. George also had primary oversight for all CDMO and CRO vendors that the companies did business with from a Quality oversight perspective.

George brings to HCATS a continuous improvement mindset for systems and processes supported by his Six Sigma training. George has more than 22 years of commercial experience in Quality Management, Technical Operations, Pharmaceutical Manufacturing and Pharmaceutical R/D. He is highly experienced in aseptic/sterile GMP manufacturing and creating Pharmaceutical Quality Systems (Quality Policy, SOPs, and Quality Culture). He is an expert in Root Cause Investigations and CAPA implementations along with Effectiveness checks, Change Control Management, Production Batch Record Reviews, Quality Agreements, and External Supplier Qualification and Quality oversight.

Greg Rhead

Senior Director, Quality
Mountain View, CA

BS (physiology) Michigan State University

Greg joined HCATS in September 2016. As Senior Director, Quality, Greg is responsible for all of Quality Assurance at the Mountain View site and is a key owner/facilitator for the Quality Task Force initiative and site-to-site harmonization efforts.

Prior to HCATS, Greg was Product Quality Manager for Commercial

Pharmaceuticals at Genentech, where he was responsible for product quality lifecycle management and monitoring, as well as global product quality strategies and improvement initiatives. Greg has also had leadership roles in both Quality and business operations at Alere, Baxter International, and the Global Coalition for Efficient Logistics

Greg brings to HCATS **25** years of strategic management expertise and technical leadership within the manufacturing and production domains. He has an outstanding track record of successfully implementing process reengineering initiatives including change management and lean Six Sigma methodologies targeted at increasing efficiency and improving output and time through effective utilization of resources.

Lori Massimore

Director, Quality Control
Microbiology/Quality Assurance

BS (microbiology) Pennsylvania State University

Lori joined HCATS as Director, Quality Control, Microbiological Laboratories in February 2016.

Lori has held a number of management-level quality and compliance roles

at companies including Dendreon and Wyeth. She has extensive technical and management experience in in the pharma and biotech industries. She has proven expertise in Quality Assurance, aseptic processing, contamination control, and Quality Systems including manufacturing deviations, non-conformance events, CAPA, change control and laboratory investigations.

Lori has extensive commercial experience from her Microbiology and Quality roles at Wyeth with respect to aseptic processing and Fill/Finish activities for pharmaceutical, biological, and vaccine products. Lori played a critical role in the commercialization of Provenge, a cellular immunotherapy treatment for prostate cancer by leading the Quality Operations and Quality Systems groups during the transition from clinical to commercial. Lori bring more than 30 years of commercial experience. Her strong communication skills, organization and attention to detail have facilitated success in implementing integrated quality systems that drive continuous improvement and sustain high quality standards.

Jim Ceglia

Director, Validation

MBA (management) Long Island University
BS (biology), State University of New York, New Paltz

Jim joined HCATS in 2009 as Director, Validation, where he is responsible for the validation and calibration of all cGMP equipment, utilities, systems and facilities to ensure compliance with FDA, ICH and EU regulations. He brings to HCATS 26 years of extensive commercial experience in the cell therapy and pharmaceutical industries with expertise in project management, validation, industrial engineering, cGMP equipment, technical support, process improvement and supervision.

Prior to joining HCATS, Jim was Senior Project Manager at Schering-Plough (now part of Merck & Co.) from 2006 to 2009, responsible for leading cross-functional teams to develop strategy and detailed project plans for the successful completion of European harmonization projects. Prior to that he spent 23 years at Novartis Pharmaceuticals with roles in technical support and validation.

Susan Saffar

Director, Quality Assurance
Allendale, NJ

MS (chemistry) St. John's University

Susan Saffar joined HCATS in March 2017. As Director of Quality Assurance, Susan is responsible for Quality Operations in Allendale, including batch record review, materials release, document management, training, and metrics.

Prior to joining HCATS, Susan was Sr. Director of Quality at Halo Pharmaceuticals, a contract development and manufacturing organization, where she was responsible for all aspects of Quality Control, Quality Assurance and Quality Compliance. Her previous experience includes various Quality, Compliance and Validation roles at Glatt Air Techniques, Blis-Tech, Innapharma and Lederle Laboratories/Wyeth.

Susan brings to the team more than 25 years commercial experience in pharmaceuticals, biologics, quality and regulations. Her experience includes managing staff, leading teams, coordinating and executing programs, overseeing QA and QC departments, monitoring compliance issues and recommending solutions, regulatory inspections, and working with both internal and external customers.

Elizabeth Burns

Director, Quality Systems

BS (Chemistry) Louisiana State University

Liz joined HCATS in March 2006. As Director of Quality Systems for both Allendale and Mountain View facilities, Liz is responsible for Auditing program (internal and external); Quality Task Force (QTF) for quality process improvements; Quality Agreements with all clients; Licensing and Accreditation for HCATS; Adverse Reactions and Customer Complaints. Liz is also responsible for reviewing regulations for not only GMP/GTPs, but also state and accreditation standards (such as AABB and FACT) to ensure that HCATS's procedures are aligned with these current standards. Over the ten (10+) years at HCATS, Liz has supported all HCATS Quality functions.

Prior to joining HCATS, Liz worked at Boots Pharmaceuticals as a QC Chemist testing raw materials and finished products; Knoll Pharmaceuticals as an R&D Scientist performing method development and testing Clinical trial materials; as well as, QA Manager person in the plant for release of commercial products; annual product review; stability studies; and customer complaints. Liz then joined Purdue Pharma as Sr. Manager of Documentation where she implemented an electronic quality management system in five US/International facilities; and later supported review of CMC sections; Validations; SOPs; and other Quality roles as an Associate Director, Research Quality Assurance at Purdue Pharma.

Liz has a strong background in cGMP/GTP with 32 years of pharmaceutical/biopharmaceutical experience in Quality in commercial manufacturing, research and development, and clinical supplies environments. This experience includes Quality support for regulatory submissions, FDA inspections, QA release of products; QC testing; Annual product review; Customer complaints and electronic systems.

Manufacturing Sciences and Technology

Brian Hampson

Vice President, Global Manufacturing Sciences and Technology; Head of the Center for Innovation and Engineering

M.E. (electrical) Cornell University

Brian Hampson founded HCATS's Center for Innovation and Engineering, created to address the important issues of scale up, automation, integration, and improved robustness within the regenerative medicine industry.

Brian has focused his career primarily on the development of first generation products and related manufacturing processes for the medical and biotechnology markets. He brings an extensive background and broad knowledge of many technical disciplines, including control systems, process automation, software, fluid systems, cell culture processes, aseptic/closed-system processing, and single-use disposable systems.

Prior to joining HCATS, Brian worked for two decades with Aastrom Biosciences in Ann Arbor, Michigan, where he held several positions, most recently as Senior Engineering Fellow, an executive level engineering position tasked with providing strategic technical leadership to cell therapy manufacturing technology. He had previously held the positions at Aastrom of Vice President, Product Development; Senior Director, Product Engineering; and Director, Instrumentation Development. Brian is a thought leader in the application of engineering principles and innovation for the needs of bioreactor systems and the manufacture of cell therapy products, and he was the chief architect for the pioneering patient-specific automation eff orts which resulted in the Aastrom Replicell System (ARS).

David O'Neill, MD

Director, Analytical Development & Medical Director

MD Ohio State University

David O'Neill brings an extensive and prestigious medical background to his research. Prior to joining HCATS, he served for eight years in various positions at New York University Medical Center, including Assistant Professor of Pathology; Director, Vaccine and Cell Therapy Core Laboratory, NYU Cancer Institute; and Attending Physician, Blood Bank, Bellevue Hospital Center. His prominent career also includes faculty and fellow positions at The Rockefeller University, The New York Blood Center, and an almost two decade term at Colombia University Medical Center, where he completed a residency in anatomic and clinical pathology, was a post-doctoral fellow in the Department of Genetics and Development and was on the Department of Pathology faculty.

He has extensive expertise in the molecular biology and biochemistry of globin gene regulation, as well as in vaccine design and compounding, immune monitoring, and the GMP production of cellular immunotherapies.

David is licensed to practice medicine in California, New Jersey and New York, and is board-certified in anatomic pathology, clinical pathology and blood banking/transfusion medicine. He has a New York State Laboratory Director Certificate of Qualification for Blood Banking, Hematology, Immunohematology and Transfusion Services. He has been a prolific writer, researcher and speaker in the fields of cell therapeutics, clinical oncology, and hemoglobin research.

Ines Mende, PhD

Associate Director, Process Development, Mountain View, CA

PhD Technical University (immunology) Munich, Germany

Ines Mende is Associate Director, Process Development at HCATS West, where she is responsible for product development of cellular therapies, including assay development and optimization for characterization of cell therapy products. She also is tasked with optimization of cell isolation and cell expansion procedures to ensure compliance with GMP processes.

Ines is an experienced immunologist with 15 years of hands-on research experience in the biotech industry and at academic institutions. She brings to HCATS her expertise in various cell based assays including flow cytometry, in vitro characterization of immune cells, cell culture, isolation of rare cell populations from human and murine blood and tissues, as well as in a variety of preclinical in vivo disease models in the areas of oncology, inflammation, and autoimmune diseases.

Prior to joining HCATS, Ines was a scientist at Aragen Bioscience where she managed all aspects of large preclinical studies in the area of inflammation, autoimmune diseases, respiratory diseases and oncology. She did her postdoctoral training in the laboratory of Dr. Edgar Engleman at Stanford University, where she successfully conducted research with a focus on dendritic cell and T cell biology leading to several publications in peer-reviewed journals.

Courtney LeBlon, PhD

Senior Biomedical Engineer, Innovation & Engineering

PhD (Mechanical Engineering), Lehigh University, PA

Courtney joined HCATS as a Process Development scientist in July 2013 and was promoted to Biomedical Engineer in August 2015. Her current responsibilities include application of automation and closed systems to cell therapy manufacturing, application of Development by Design (DbD) and Risk Management principles, process mapping, cost of goods modeling, quality risk management, and change management/comparability assessment.

Courtney joined HCATS after completing her PhD. As a graduate research assistant, she investigated the effects of substrate elasticity on long-term mesenchymal stem cell (MSC) culture, the effects of polymer molecular orientation and biodegradation on MSC culture/differentiation, and the influence of mechanical stimulation on MSC differentiation.

Courtney received her B.S. in Biomedical Engineering from The College of New Jersey and PhD and M.S. in Mechanical Engineering from Lehigh University.

David Smith, PhD

Senior Biomedical Engineer, Innovation & Engineering

PhD (Regenerative Medicine), Loughborough University, UK

David Smith joined the Innovation & Engineering Center at HCATS's Allendale location to combine his engineering and statistical knowledge in cell processing to improve manufacturing processes. His core vision is to create automated and closed systems for 'needle to needle' processes. This will have significant impact on the time, cost, and reproducibility associated with advancing cell therapies to commercial success.

Before joining HCATS in 2015, David studied in the Centre for Biological Engineering while at Loughborough University. David's principal research collaborating with CM-Technologies, Tampere, Finland, utilized automated live cell imaging for process control and development. This interdisciplinary research combined David's biochemical engineering background with more recent knowledge in cell biology through the use of pluripotent and multipotent stem cells. This provided David with expertise in automated cell culture, along with a range of analytical techniques such as flow cytometry, fluorescence-activated cell sorting (FACS), immunohistochemistry, imaging and PCR. In developing a Process Analytical Technology (PAT) for in-process use, David applied Quality by Design (QbD) approaches to ensure statistical resolution. He brings this statistical knowledge along with automated processing to enhance robustness and reproducibility of processes to supplement HCATS's own Development by Design (DbD) paradigm.

David received his MEng in Biochemical Engineering from the University of Bath, UK.

Silky Kamdar, PhD

Scientist, Process Development

PhD (Neuroscience and Cell Biology) Rutgers University

Silky Kamdar joined HCATS as a Scientist in the Process Development department in September 2014. Silky is responsible for development and validation of assays that demonstrate integrity and function of cell therapy products and contributes to the development of Strategic Manufacturing Assessments for clients. She has served as a subject matter expert for quality and manufacturing for client process development projects.

Silky's experience in cell and molecular biology comes from her more than eight combined years of post-baccalaureate and pre-doctoral training at Rutgers University. During her pre-doctoral training, she studied neurodevelopment and cellular characteristics in genetically modified mouse models of autism spectrum disorders. In addition, Silky's post-doctoral research and development experience in the medical devices and diagnostics industry at Fortune 500 Company Becton Dickinson makes her uniquely qualified as a process development scientist at HCATS, where her role includes troubleshooting during assay development and requires a thorough understanding of the regulatory process involved in product development, from manufacture through commercialization.

Silky received her M.S. and B.S. in Biochemistry from University of Mumbai, India.

Tonye Briggs, PhD

Process Development Specialist

PhD (biomedical engineering) New Jersey Institute of Technology

Tonye joined HCATS as a Process Development Specialist in December 2014. Tonye works within a cross-functional team environment to develop and optimize processes for the manufacture of cellular therapeutics. Specifically, her responsibilities include developing assays for cell potency and managing projects and providing expertise to clients for technology transfer.

Tonye joined HCATS after a postdoctoral research fellowship at the University of Pennsylvania, Department of Bioengineering. Her research focused on investigating methods to prevent and mitigate post-surgery complications of infection and pain by conducting preclinical studies using biomaterial drug delivery systems and medical devices. For her doctoral research she Investigated bone tissue regeneration applications using human mesenchymal stem cells (hMSCs) on 2-D polymer films and 3-D scaff olds.

Tonye received her BS from Case Western Reserve University in Ohio, and her MS and PhD from the New Jersey Institute of Technology, all in Biomedical Engineering.

Christopher McSorley

Product Development Scientist

B.A. (applied ecology), University of California, Irvine

Christopher McSorley is a Product Development Scientist at HCATS, where he is responsible for the development and testing of full-scale procedures for the manufacture of cells and tissues intended for clinical use.

Chris brings a breadth of cell culture experience to HCATS, owing to his broad background in cellular biology, molecular biology, in vivo and clinical studies. In his years as a researcher, he has gained extensive experience in the isolation and expansion of cells from human blood products and tissues and mammalian cell culturing with various cell types. His past experience managing large-scale clinical projects under GMP conditions makes him a valuable asset to HCATS's science team.

Chris began his career as a Research Associate at the University of California, Irvine Environmental Microbiology and Genetics Lab before taking a position at Sugen Inc., a biopharmaceutical company that discovered and developed small molecule drugs. He soon joined Iconix Biosciences, becoming instrumental in coordinating the company's first clinical trial before moving to Entelos, Inc., where he managed a high-throughput RNA microarray expression analysis facility. He later joined CardioDX, where he managed the Sample Processing group through the course of two clinical trials and the launch of the company's first commercial diagnostic product.

Product Stewardship and Manufacturing Support

Catherine McIntyre, PhD

Senior Director, Global Product Stewardship and Manufacturing Support

PhD (Virology) University of Sheffield, UK

As Senior Director, Global Product Stewardship and Manufacturing Support, Catherine McIntyre is responsible for all technology transfer activities, process monitoring, manufacturing process troubleshooting and working closely with her engineering and science colleagues to improve manufacturing processes. Catherine combines her unique technical background in cell therapy research and manufacturing with her team and program management skills. She aims to meet and exceed client expectations by supporting communication between clients and HCATS associates during ongoing projects, keeping projects on task, and providing scientific input as needed.

Catherine is an expert in cell therapy product development with more than two decades of biotech experience in R&D, management, Systems Validation, product development and scale-up, project management and cGMP manufacturing.

Before she joined HCATS, Catherine held several positions at BD Biosciences, most recently as Manager, Systems Validation and Application Notes, Systems Engineering, R&D, where she was responsible for introducing and establishing Planning and Leading project methodology as a standard approach for projects undertaken by the System Validation team. She was also responsible for the planning, execution and writing of application notes in collaboration with product managers and collaborators. Catherine also established a cGMP compliant laboratory within the Cell and Tissues Technologies Department at BD. Prior to BD, Catherine worked at Novocell Inc., Atairgin Technologies Inc., and ICRF Cancer Medicine Research Unit, St James' University Hospital, UK.

She performed nine years of academic research experience in tumor immunology, cancer vaccine development and dendritic cells at the Institute for Cancer Studies, University of Sheffield, UK. She has also published fourteen peer-reviewed publications and received one patent.

Adam Pegueros

Senior Associate, Manufacturing Sciences & Technology

BS (biotechnology) University of California, Davis

Adam joined HCATS as Senior Associate, Manufacturing Sciences and Technology in May, 2016. In this role, he works closely with clients and interdepartmental teams to facilitate external and internal knowledge transfers. Adam tracks in-process data, process gaps, and risk assessment for knowledge transfer; generate documents, tracks deadlines, and supports research and development activities; train technicians and reviews and approves master batch records, and acts as a subject matter expert to troubleshoot and advise for manufacturing teams.

Prior to his current role, Adam moved up the ranks at HCATS, including roles as Cell Therapy Specialist I, II, and III, and as Senior Manufacturing Associate. His previous roles include Histology Assistant at Oppenheimer Urologic Reference Laboratory and Laboratory Assistant in the Department of Pediatrics at University of California, Davis.

Adam is an experienced technical writer and project lead with more than seven years of laboratory and GMP manufacturing experience. He contributes a proven record of leading operational projects, process and equipment validations, and process improvement. His strong understanding of contract GMP manufacturing and his in-depth laboratory experience enable Adam to drive projects to completion. Adam has more than five years of experience collaborating with Development and Manufacturing departments on cell culturing and engineering methods.

Account Management

Mark Flower

Executive Director of Sales and Marketing

University of California San Diego

Mark joined HCATS in September of 2017, as the Executive Director of Sales and Marketing. In this role he leads marketing, communications, industry intelligence, sales and account management efforts. Mark has over 12 years experience working in the field of oncology, immunotherapy, cellular therapy and bioprocessing.

Prior to joining HCATS Mark worked at Terumo BCT as Senior Manager, Global Strategic Marketing, in the Therapeutic Systems business unit. In this global role he was focused on market research, business development opportunities and established consulting services with developers of cell based gene and immunotherapies. In previous roles Mark successfully launched and maintained commercial responsibility for multiple devices and technologies in the field of stem cell collection via leukapheresis, cell isolation, cell processing and manufacturing. His relationships extend to leading academic and research centers that serve as the clinical trial sites for numerous innovative cell therapies.

Mark is a member of the International Society for Cellular Therapy (ISCT), the Society for Immunotherapy of Cancer (SITC), and graduated from the University of California, San Diego with a BS in Biological Science.

George S. Goldberger, M.B.A.

Vice President, Business Development

M.B.A. (finance) Wharton School of the University of Pennsylvania

George S. Goldberger is HCATS's Vice President, Business Development. Prior to the acquisition of HCATS by NeoStem in 2011, he was HCATS's Chief Business and Financial Officer. He held these positions since March 1999.

Before joining HCATS, George was President and Chief Executive Officer of Goldberger & Associates Inc., an international management consulting firm with off ices in New York, Budapest, Bucharest and Kiev where they served multinational companies with a focus on health care services. Through Goldberger & Associates, George assisted National Medical Care, now part of Fresenius Medical Care, in establishing and developing dialysis center operations in Europe. Prior to that, George was in charge of mergers and acquisitions at Figgie International, Inc., a diversified conglomerate, today known as Scott Technologies Inc.

Cenk Sumen, PhD

Senior Manager, Business Development

PhD (microbiology and immunology) Stanford University School of Medicine

Cenk Sumen joined HCATS in 2014 as Manager, Technology & Business Development. He is tasked with business development, technology assessment, customer relationship management, and various sales and marketing functions for HCATS.

Most recently, Cenk was Business Development Manager at PerkinElmer where he supported PerkinElmer's Drug Discovery Services business. Other prior positions included Technical Sales Specialist at STEMCELL Technologies, where he provided technical consultative sales for stem cell culture and diff erentiation systems, and Technical Consultant, Sales & Marketing at Life Technologies, where he served as scientific, strategic, sales, and marketing consultant for the Dynabeads technology platform based in Norway.

At Stanford University School of Medicine, Cenk studied T cell activation at the immunological synapse. He completed his postdoctoral work, first, at the Center for Blood Research (now IDI, Harvard Medical School) studying in vivo lymphocyte dynamics, and then, as a Cancer Research Institute Fellow at Memorial Sloan-Kettering Cancer Center, building a two-photon imaging system to study cancer immunotherapy. Cenk received his B.S. in biology from MIT.

Project Management

Frank Costanzo

Senior Director, Project Management

B.A. (history) Rutgers University

As Senior Director, Project Management, Frank is responsible for the day-to-day management and execution of client-specific project activities at HCATS. As the leader of HCATS's Program Management Off ice (PMO), Frank is driven towards "getting things done" and driving results – through collaboration, partnerships, and relationships. With an enthusiastic and genuinely friendly attitude, Frank radiates a sincere passion for delivering value and benefits to his customers.

Frank is a seasoned project manager with over 16 years of experience in the pharmaceutical/biotechnology industry. Prior to HCATS, Frank worked at Merck & Co., Inc. (formerly Schering-Plough). As a project manager, he worked collaboratively with cross-functional, global teams to resolve complex problems and build consensus around appropriate solutions. The programs he managed encompassed multiple therapeutic areas and dosage forms. While at P.F. Laboratories (a division of Purdue Pharma), he established a PMO that managed a dynamic portfolio of 60+ site-related capital projects, regulatory (FDA & DEA) compliance projects and re-engineering/continuous improvement initiatives.

Frank is certified as a Project Management Professional (PMP) by the Project Management Institute.

Frank earned a Project Management Certification from the Rutgers University Center for Continuing Professional Development.

James DeLillo

Senior Project Manager

B.S. (industrial engineering) New Jersey Institute of Technology

Jim DeLillo joined HCATS in February 2016. He manages projects to support the development and commercialization of cellular therapies through customized services such as process development, technology/method transfer, validation, product manufacturing, distribution, storage and transportation.

Prior to joining HCATS, Jim held Senior Project Manager and consultant roles at pharmaceutical and medical device companies including Becton Dickinson, Dendreon, and QPharma. Additionally, he worked as Manufacturing Systems Specialist on computer systems at Wyeth (now Pfizer). In addition to his pharmaceutical background, Jim is internationally recognized as a photographer, photojournalist, sales rep, and industrial engineer for various organizations. His experience includes 10 years as an independent consultant and expert in Bar Code Systems, RFID, Factory Automation, Inventory Control Systems and Manufacturing Execution Systems (MES).

Jim has many specialized certifications that reflect his diverse career, including Stanford Advanced Project Management (sCPM), Certified Quality Engineer (CQE), Certified Software Quality Engineer (CSQE) and Certified Quality Manager (CQM).

Mikhail M. Baklashov

Project Manager

BS (chemistry) San Jose State University

Mikhail M. Baklashov joined HCATS in November 2016. As Project Manager, Mikhail is responsible for the management of multidisciplinary project teams from Development through Technology Transfer and cGMP Manufacturing. He is the liaison between HCATS and our clients, guiding projects from initiation through close out.

Prior to joining HCATS, Mikhail served as Project Manager for Comparative Biosciences, Inc., where he managed implementation process for over 50 projects, ensuring successful on-time completion, while maintaining compliance with SOPs, GLPs, scope, and cost specifications. He also increased company revenue by utilizing cost of goods analysis. Mikhail has also served as Associate Scientist/Manufacturing Lead for Advanced Cell Diagnostics, Inc. and Production Chemist Lead at Nanosys, Inc.

Mikhail brings to HCATS experience in off ice and laboratory management, training, strategic planning, buying, budgeting, and financial reporting. He has had success in leading teams to meet production/service deadlines, resolving conflicts, and guaranteeing accuracy to maintain client satisfaction.

Wesley Harlow

Project Manager

MBA (financial management) Iona College

Wesley Harlow joined HCATS in November 2016. As Project Manager, Wesley is responsible for the management of multidisciplinary project teams from Development through Technology Transfer and cGMP Manufacturing. He is the liaison between HCATS and our clients, guiding projects from initiation through close out. Wesley holds a PMP (Project Management Professional) certification.

Prior to joining HCATS, Wesley spent seven years as a Senior Associate Scientist/Project Leader with Pfizer Vaccines Research, where he served as the project lead for the introduction of new innovative biotechnology, especially automation technologies. He also previously worked as Associate Scientist for the National Institute of Health. Wesley is the co-author of a paper titled “Phylogeography Relationships of the neotropical Anopheles Triannulatus complex (Dipteria: Culicidae) supports deep structure and complex patterns,” published in the journal Parasites and Vectors in 2013.

Wesley’s experience in project and team management, development, validation and optimization of biofunctional-assays, and FDA compliance make him a valuable addition to the HCATS team and his passion for results enables him to drive projects on time and within budget.

Wesley also has a BS (biology) University at Albany, State University of New York.

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