CYNTHIA DUKES

Injecting Hope into Fight Against Infectious Disease

Cynthia Dukes has devoted most of her career to designing and implementing clinical studies that have contributed to the successful development of new vaccines and treatments for infectious diseases and cancer. Throughout her career in pharma, she has participated in more than 40 INDs, leading to eight product approvals, including five vaccines, two oncology products and one immunoglobulin.

And now, since joining ICON Clinical Research, a global CRO, she has provided oversight and guidance on all vaccine and infectious disease studies at ICON, which have contributed pivotal data to the approval of 11 additional vaccines.

During her career in vaccine development, Ms. Dukes has been at the cutting edge of combating new and emerging infectious diseases. While on the clinical side she had the opportunity to work on the first Phase I study of the first HIV treatment and the first HIVvaccine candidate in the mid-late 1980s. She's also worked on one of the first HIB vaccines tested in infants. After moving to the biopharma side of the industry she participated in the full clinical development of the second HIB vaccine approved for infants. Most recently, her team at ICON has done a lot of work on the development of vaccines for pneumococcal disease, seasonal and pandemic influenza, C Diff infection, meningococcal disease, anthrax, and several other antigens to combat bioterrorism. Overall, she has touched more than 40 vaccines in some way during her career.

Driven to innovate by

BRAINSTORMING

Her dedication to vaccine development has not gone unnoticed within the biopharma industry. In 2014, she was voted one of the World's Most Influential People in vaccines, following a global survey conducted by the vaccine industry organization VaccineNation (vaccinenation.org). Honorees were chosen based on their career achievements whether it was groundbreaking discovery and research or innovation, funding, lifetime dedication, or simply because they might have inspired others to do well. The winners included representatives from all aspects of vaccines, including the industry, governments, philanthropy, academia, and even show business. Ms. Dukes was the only representative from a CRO included on the list.

Logical. Integrity.

Cynthia Dukes has been at the cutting edge of combating new and emerging infectious diseases through her work in vaccines.

Also, thanks to her leadership, in April 2014 ICON was awarded the Best CRO at the Vaccine Industry Excellence Awards, which honors individuals, organizations, and initiatives that have made significant contributions to innovation in the field of vaccines.

Ms. Dukes has also been a driving force behind ICON's range of services in niche and core therapeutic areas. During her 15 years at ICON, she has been instrumental in improving ICON's methods of performance and introducing new services, and has helped to strengthen the quality of relationships with clients and investigative sites. In 2015, she was honored with ICON's Excellence in Leadership Award.

Ms. Dukes also received the Distinguished Alumni Award from her alma mater Baylor College of Medicine in 2015. The Distinguished Alumni Award is presented to alumni who make outstanding contributions to biomedical and/or medical science through clinical service, research, education and/or administrative leadership.

Getting to know...

Cynthia M. Dukes

TITLE: VP, Global Project Management
COMPANY: ICON Clinical Research
EDUCATION: Baylor College of Medicine
FAMILY: Husband, three children
AWARDS/HONORS: One of the world's Most Influential People in Vaccines, Vaccine Nation, 2014; Distinguished Alumni Award, Baylor College of Medicine, 2015
ASSOCIATIONS: Association of Clinical Research Professionals; Metrics Champion Consortium
SOCIAL MEDIA:

Despite a hectic workload at ICON, which includes countless hours of global travel to meet clients, Ms. Dukes has always found the time to expand her knowledge and lend her expertise in the field of vaccines to further aspire innovative vaccine development.

She has been a member of the Site Forum within the Association of Clinical Research Professionals (ACRP), where she is engaged in building relationships with site networks and clinical professionals. Ms. Dukes also has been a committee member of the Metrics Champion Consortium, where she was engaged in the development of clinical site metrics.

In addition, Ms. Dukes has devoted time outside of ICON to educating the next generation of researchers about the range of exciting careers in science, medicine, clinical research, and vaccines. Through presentations and workshops at a range of schools in her local community in San Antonio, Texas, she has inspired countless children to enter into biomedical science fields.

Ms. Duke has also been a judge in local science fairs for many years and has mentored underprivileged girls through the highly successful Big Brothers Big Sisters of America program.

"My management style is collegial and includes continual mentorship," she says. "I hopefully inspire others by being the best I can be and by sharing my experiences and then expecting the best from my teams."

DR. THOMAS LARGE

Blazing New Trails in Drug Discovery

Thomas Large, Ph.D., is someone who embraces contrarian thinking. As senior VP of discovery and preclinical research at Sunovion Pharmaceutical, he likes to disrupt current thinking and ways of doing business to help achieve the goal of developing new breakthrough treatments.

Dr. Large is a proponent of becoming comfortable with strategic and calculated risks, as opposed to gambling, and believes that research can learn a lot more from taking new paths than following traditional routes. This thinking has led Sunovion to pioneer a systems-based approach to finding new psychiatric drug candidates. It is a unique approach to discovery in the CNS space based on a systems neurobiology platform that helps facilitate rapid clinical development. Specifically, Dr. Large and his team take a phenotypic, or behavior-based, approach that drives medicinal chemistry. The middle step is what he calls a systems neurobiology piece, where he and his team characterize molecules at the circuit level. He and his team look at what's happening in the brain using imaging, expression changes, and leverage advances in big data analysis to identify and optimize new drugs candidates.

"Within discovery, I enjoy deconstructing dogma processes and building them back up in new ways," Dr. Large says.

Dr. Large, who joined the company in 2007, says the science Sunovion is working on is his biggest career highlight to date.

"Our approaches are truly different, exciting, and productive," he says. "We are able to work much times faster than traditional approaches to uncover new mechanisms of action and solutions. Sunovion has pioneered a unique approach to discovery in the CNS space based on a systems neurobiology platform that helps facilitate rapid clinical development."

The company's discovery research focus is on psychiatric indications such as schizophrenia, depression, cognitive function, and bipolar disease. The company is also taking a fresh approach to drug discovery by partnering with external biotech, contract research, and academic organizations to find potential treatments in areas of high unmet need. By engaging external innovation partners, company researchers hope they will be able to more effectively turn ideas into new drugs.

Dr. Large has advanced this unique approach to discovery, which takes a target-agnostic view in contrast to target-based discovery, which is conducted by most of the industry. He and his team have built an exciting library of compounds they continue to mine. By moving away from the standard target-based discovery model that has been in place for the last 30 years, he and his team are screening all targets simultaneously in a living animal allow, which allows them to see activities by behavioral changes that couldn't be realized if the focus was on a single target. Because of this thinking, his team can better understand the range of possible therapeutic indications and also get a sense of the measures to take in the early clinical space.

He would like to be remembered for helping to lead a new revitalization of CNS drug discovery, and his legacy is already coming true as Sunovion's pipeline has a number of very exciting molecules that have advanced since the company was established five years ago.

He also believes that discovery is a group effort.

"I make sure I take the time to inspire others around me," he says. "I recognize that even small amounts of encouragement on a daily basis can make a big difference to our preclinical and discovery team members. I try to reinforce that they are headed in the right direction, doing what no one else is doing, and moving forward in the face of natural challenges in the discovery process." PV

Getting to know...

Thomas Large, Ph.D.

TITLE: Senior VP, Discovery and Preclinical Research

COMPANY: Sunovion Pharmaceuticals Inc.

EDUCATION: Ph.D., Neurobiology/Physiology, Northwestern University; completed a Howard Hughes postdoctoral fellowship at the University of California, San Francisco

HOBBIES: Fly fishing, gardening, sailing, racing keel boats

BUCKET LIST: Fly fishing in Mongolia

AWARDS/HONORS: Spirit of Innovation Award, Sunovion

Curious. Maverick.

Dr. Thomas Large is aiming for "hit it out of the park" innovation that disrupts current ways of thinking and doing business and leads to big breakthroughs.

Driven to innovate by

BREAKTHROUGH TREATMENTS

Empathetic. Committed.

DR. JANE OSBOURN

Biologic Breakthroughs

Getting to know...

Jane Osbourn, Ph.D.

TITLE: Site Leader, VP R&D MedImmune Cambridge

COMPANY: MedImmune

EDUCATION: BA, Natural Sciences, University of Cambridge; Ph.D., University of East Anglia, John Innes Institute

FAMILY: Her incredibly supportive husband, John; two children who she constantly learns from; parents for ensuring she focuses on doing the right thing

HOBBIES: Running, netball, gardening

AWARDS/HONORS: CEO awards for best research publication and contribution to making AstraZeneca/MedImmune a great place to work; Business Woman of the Year, Institute of Director, 2010, for work in supporting the merger of Cambridge Antibody Technology and MedImmune

SOCIAL MEDIA:

Dr. Jane Osbourn is exceptional at putting the pieces together to make significant contributions to the discovery and development of numerous clinical candidates.

Driven to innovate by PATIENTS

As a member of the MedImmune leadership team, Jane Osbourn, Ph.D., has a very clear purpose and commitment: to see the company's medicines reach patients as quickly as possible and to help ensure the company delivers one new biologic medicine to patients every year.

Dr. Osbourn leads the company's global biosuperiors team and portfolio, which involves the assessment of opportunities to create differentiated biologic molecules with superior efficacy to target clinically validated targets. She oversees more than 500 scientists and drug development professionals based in Cambridge, U.K.

A phage and ribosome display expert with significant experience in antibody engineering and drug discovery, Dr. Osbourn has helped to advance the field of human monoclonal antibody drug research and development — most recently focused in the area of biosuperiors — and has made significant contributions to the discovery and development of numerous clinical candidates.

Most recently, her team's work was published in 2016 Cancer Cell explaining the first biparatopic antibody to enter the clinic. This is a HER2 antibody-directed conjugate that is being assessed as a potential therapy for breast cancer patients.

Her greatest career highlight to date is seeing the development of the company's phage display technology deliver around 100 clinical candidates.

Early in her career at MedImmune, Dr. Osbourn was an integral part of the team that created and built Cambridge Antibody Technology's (CAT) extensive phage antibody libraries, which were used to generate two marketed drugs: Benlysta, a FDA-approved treatment for lupus, and Humira, which is approved to treat moderate-to-severe rheumatoid arthritis, among its many indications. She also was integral to establishing the ribosome display as part of the company's drug discovery platform.

In addition to her contribution to science, Dr. Osbourn is an inspirational and highly respected leader. She played a central role in creating a motivated organization during the integration of the CAT team into the company's headquarters in Maryland in 2008. Her role in building a successful global business with an innovative, commercially valuable pipeline and a creative, energetic, scientific culture was recognized in 2010 when she was awarded the Institute of Director's East of England Businesswoman of the Year Award.

In 2013 AstraZeneca, MedImmune's parent company, announced it would be building an R&D hub and at its corporate headquarters in Cambridge, U.K. This involved moving MedImmune's entire team to the new premises, with AstraZeneca colleagues. Dr. Osbourn has played a pivotal role in this initiative, chairing the company's new site leadership team, which oversees all aspects of the project resulting in more than 2,000 staff members coming together in one new location.

She is committed to ensuring all employees are provided with development opportunities and to maintaining an internal company culture that allows individuals to thrive and work to the best of their abilities.

Despite her busy schedule, Dr. Osbourn remains completely grounded and in touch with the many staff who work around her. She always tries to see things from a variety of different points of view, noting that innovation thrives when there is diversity of thought. She motivates her teams by reinforcing the company's vision, defining the goals, communicating the plan, and checking in to ensure everyone understands what their role is and how they feel about their contributions.

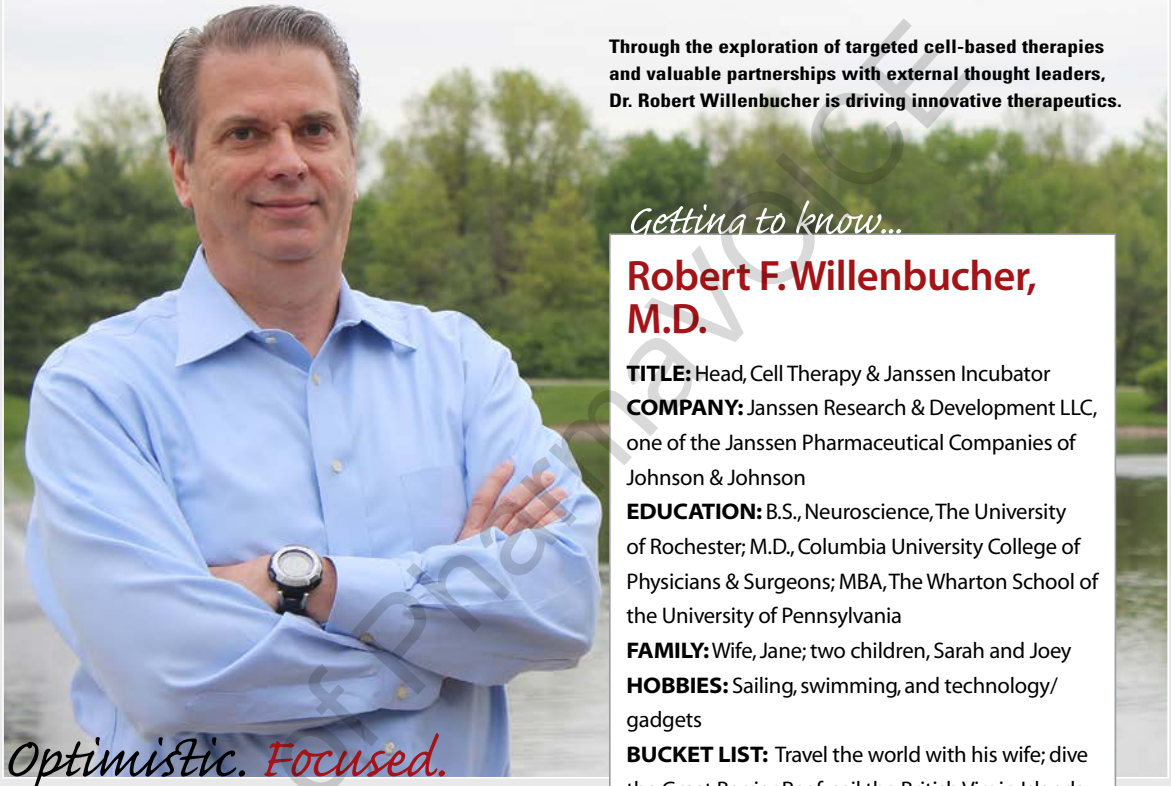
Dr. Osbourn also commits time to helping the company's young scientists navigate the research landscape as well as understand how to do things effectively, work as part of a team, assert their ideas, and stay focused.

She believes the greatest innovations lie in immunotherapies for cancer, which provides a huge opportunity to deliver patient benefits. She also notes that digital healthcare and the change in patients' understanding of their overall health status will drive better holistic care in the coming decade.

She contributes to AstraZeneca's UK science policy work and has presented at a number of UK parliamentary committees. In addition, Dr. Osbourn has long been an active supporter of MedImmune's commitment to public education and science outreach and strives to maximize all opportunities to inspire children and students to consider a career in science. In 2014, she was elected to the board of the UK BioIndustry Association (BIA), and in January 2016 she took over the role as chair of the board, becoming the first female chair in the history of the BIA. PV

DR. ROBERT WILLENBUCHER

Innovating at the Intersection of Science and Business



Through the exploration of targeted cell-based therapies and valuable partnerships with external thought leaders, Dr. Robert Willenbucher is driving innovative therapeutics.

Optimistic. Focused.

As head, cell therapy and Janssen Incubator, at Johnson & Johnson, Robert Willenbucher, M.D., is driving the development of a potentially first-in-class cell therapy product, palucorcel, for the treatment of geographic atrophy secondary to age-related macular degeneration, a devastating disease for which no approved therapy currently exists. Currently, the program, which began as a Johnson & Johnson Development Corp.-funded internal venture, is in Phase IIb trials.

He and his team have had to overcome the numerous challenges inherent with first-in-class therapeutics as well as navigate through the complexity of a therapy that requires targeted delivery of cells, including developing the devices, surgical procedures, and the cells themselves. The product team also is dealing with the manufacturing and supply chain challenges that occur for novel components not part of an existing platform or infrastructure.

Despite the many obstacles, advancing palucorcel into late-stage clinical development has been Dr. Willenbucher's biggest career highlight.

"The entire clinical journey has been quite innovative, often requiring us to build from the ground up procedures, processes, and equipment for this novel product," he says.

Members of the cell therapy team credit Dr. Willenbucher's intellect and his ability to manage a network of internal and external support partners with moving palucorcel from a small venture project into development with a robust team supporting its success.

"Innovation is about accomplishing big things that bring value to people," he says. "Achieving big things is about focusing on the small things that must be accomplished today to continue on the path to innovation tomorrow."

Driven to innovate by

MAKING A DIFFERENCE

His strategic approach to science led to the development of the Janssen Incubator, an entrepreneurial-like business model that encourages prudent risk-taking by investing in novel assets, platforms, and technologies as a means to discover and deliver transformational medicine for diseases where high unmet medical needs still remain. Operating within Janssen Research & Development, the Janssen Incubator allows researchers to explore strong ideas outside of the core Janssen areas of interest and focuses on milestone-driven discovery, which enables critical decision making to occur quickly. Under Dr. Willenbucher's leadership, the incubator has invested in six ventures focused on autism spectrum disorder, lupus, MRSA, chronic pain, a new approach building on nature's chemical diversity to generate a drug discovery space for small-molecule research, and a platform to develop therapeutics with reduced side effects.

He believes the Janssen Incubator provides one of the essential factors necessary for innovation — the ability to be creative and take risks.

"Organizations that successfully innovate are the ones that provide a circumscribed environment that is protected from the constraints imposed by the near-term needs of the mature business," he says. "Teams that operate in this space have very clear objectives and receive ring-fenced funding based on milestone achievement."

Through the development of the Janssen Incubator, he is truly changing the face of healthcare and setting the stage for a new operating model that will make significant contributions to human health in the future.

"I always focus on the higher order purpose: the patients who are in need of the treatments we are developing," he says. "I put them first, and would like to be remembered for my commitment to innovation as a way to develop treatments for people with significant medical need." PV

Getting to know...

Robert F. Willenbucher, M.D.

TITLE: Head, Cell Therapy & Janssen Incubator
COMPANY: Janssen Research & Development LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson
EDUCATION: B.S., Neuroscience, The University of Rochester; M.D., Columbia University College of Physicians & Surgeons; MBA, The Wharton School of the University of Pennsylvania
FAMILY: Wife, Jane; two children, Sarah and Joey
HOBBIES: Sailing, swimming, and technology/gadgets
BUCKET LIST: Travel the world with his wife; dive the Great Barrier Reef; sail the British Virgin Islands
AWARDS/HONORS: Multiple winner of Johnson & Johnson Standards of Leadership Award; NIH Physician Scientist Award
SOCIAL MEDIA:

DR. JESÚS GÓMEZ-NAVARRO

One Goal: Cure Cancer

Jesús Gómez-Navarro, M.D., left his life in Spain to achieve one singular goal: cure cancer.

At the early age of 8 he became infatuated with medicine and disease, spending hours pouring through the pages of his parents' encyclopedia reading about illnesses, their causes, and how to treat or cure them.

Many years later, after completing his medical training, Dr. Gómez-Navarro began his medical career in the ER of a Spanish hospital followed by time spent studying and treating cancer patients, all the while knowing that these experiences as an individual physician were as much about learning how to mobilize a greater, team-based whole. He soon completed a post-doctoral fellowship in gene therapy, leading to the pharmaceutical industry and Pfizer, which was embarking on a new approach around biologics and immunotherapy.

"The biggest highlight of my career to date is the fate of several metastatic melanoma patients treated in one of my first clinical trials conducted in the early 2000s at Pfizer with a checkpoint inhibitor," he says. "They entered the trial with widespread melanoma, back then akin to a death sentence, and left with extraordinary, sustained responses. Now, more than 10 years later, several are still alive and thriving. Getting to know them and their personal stories provided me with profound satisfaction, and propels me forward."

Now as VP and head of clinical research and development, oncology TAU, at Takeda Pharmaceuticals, he oversees a global team of clinicians responsible for clinical trial design, medical monitoring, and interpretation.

Dr. Gómez-Navarro joined Millennium Pharmaceuticals in 2009 as senior director, oncology clinical research and global clinical lead for Ninlaro (ixazomib), which was approved by the FDA in November 2015 for the treatment of multiple myeloma. Millennium, after being acquired by Takeda in 2008, was folded into the overall organization in 2013.

Dr. Gómez-Navarro has steered Takeda Oncology's clinical research organization through a series of significant transformations. Through his leadership, the company has created an environment where people are able to make a valuable contribution.

His scientific acumen, background as an oncologist, and collegial spirit made him the best choice for this leadership role. He is adept at leading and managing physicians and scientists across a diverse clinical continuum, all the while fostering an open approach to distinct viewpoints from team members or executive colleagues.

Peers say he has created an environment where people can thrive individually, but more importantly, succeed as part of an integrated team.

Getting to know...

Jesús Gómez-Navarro, M.D.

TITLE: VP, Head of Clinical Research & Development, Oncology TAU

COMPANY: Takeda Pharmaceuticals

EDUCATION: Master, Palliative Care, and Fellowship in Medical Oncology, Universidad Autonoma; M.D., Universidad Complutense

FAMILY: Parents, Jesús Gómez Lozano and Maria Teresa Navarro Rodriguez; sisters, Esther and Maria Teresa; spouse, Emilio Coyra

HOBBIES: New age music, reading, traveling, great food and wine

BUCKET LIST: A singular aspiration: cure cancer

AWARDS/HONORS: Takeda-MIT Leadership Academy, 2015; Pfizer Global R&D Performance Award, 2005

ASSOCIATIONS: American Association of Cancer Research, American Society of Clinical Oncology, American Society of Hematology, New York Academy of Sciences, Society for Immunotherapy of Cancer, American Association for the Advancement of Science

SOCIAL MEDIA:

Passionate. Team player.

Dr. Jesús Gómez-Navarro's knowledge and passion for the field of oncology inspire his peers inside Takeda as well as those outside the company.

"Being part of a group of talented, coordinated healthcare professionals holds the highest likelihood of success for a patient," he says. "Helping people in my team reach their full potential is a responsibility that I take very seriously. We all have strengths and weaknesses, and those can play very differently depending on the assignments and the opportunities we are given. As a people manager, I strive to facilitate career paths to peak performance and job satisfaction, which requires excellent communication and emotional intelligence."

Dr. Gómez-Navarro says his current focus is to establish his group as a best-in-class clinical research department that attracts, retains, develops, and empowers outstanding oncology physicians and scientists from around the world. He wants his team to be science-driven, patient-centric, entrepreneurial, and passionate about the aspiration to cure cancer.

"I believe that we can cure cancer, or at least most cancers, in my life time," he says. "Every day I reflect on this, and I consider how to accelerate that progress."

Dr. Gómez-Navarro says he strives to nurture a culture of innovation, maintain organizational effectiveness, and a commitment to transformative R&D — through partnerships and other non-molecule innovations — which are the three important pillars to move the needle in terms of his goal to cure cancer.

He would like to be remembered as a caring physician-scientist, a team-player, someone who is always looking out and forward, and striving to keep a broad perspective, inclusive of the industry and of healthcare across the globe. Colleagues say he is already living his legacy. PV

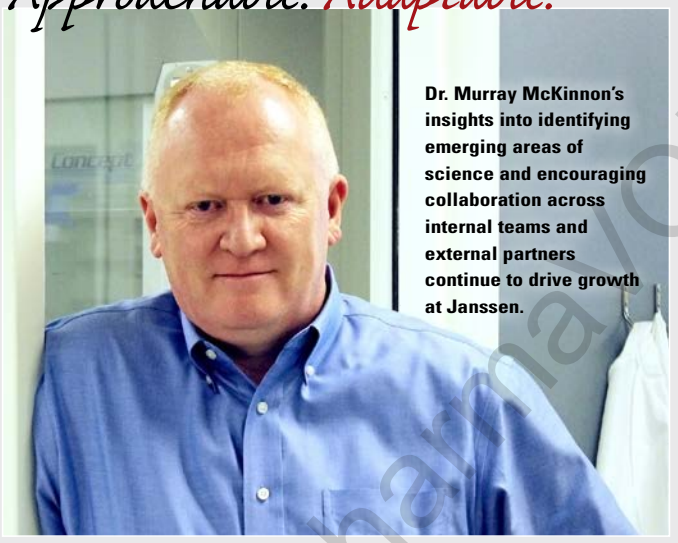
Driven to innovate by

NEED FOR A CURE

DR. MURRAY MCKINNON

Team Building Meets Drug Development

Approachable. Adaptable.



Dr. Murray McKinnon's insights into identifying emerging areas of science and encouraging collaboration across internal teams and external partners continue to drive growth at Janssen.

Murray McKinnon, Ph.D., VP, head of Immunology Discovery & Janssen Immunosciences, Janssen Research & Development, has a two-pronged approach to success: he combines tremendous team-building skills with his innovative discovery and development expertise.

In addition to leading a complex global organization that spans both coasts of the United States and a European base, Dr. McKinnon plays a critical role in shaping the strategy for harnessing external innovation to identify early science that can be translated into groundbreaking medicines to treat immune disorders. He has provided strategic oversight and led several key external alliances that have pushed the field forward by developing innovative platforms and technologies to target diseases.

When Dr. McKinnon assumed leadership of the discovery immunology team based in La Jolla, Calif., he worked skillfully to build a "one team" culture between the employees in La Jolla and Spring House, Pa. This approach helped to leverage the technical capabilities and scientific skill sets across both sites and build a team that is united despite geographic boundaries.

Another example of great teamwork occurred when Janssen collaborated with Phenex Pharmaceuticals AG on a novel nuclear receptor; the project ran smoothly, allowing the teams in Spring House, La Jolla, and Heidelberg, Germany, to build strong scientific partnerships that resulted in a high-quality new molecular entity now in preclinical development for treating psoriasis.

Dr. McKinnon continually puts his people first with a focus on individual and career development. Despite a full schedule, his door is literally always open for anyone in need of counsel, coaching, or a bit of guidance.

"I find that staying connected to the team and maintaining an informal approach are important for building trust and openness," he says.

A large part of Dr. McKinnon's success can be attributed to his innate ability to energize the scientists who surround him; he understands their goals and provides an environment that enables colleagues to tackle cutting-edge challenges in immunological diseases. He has been an outstanding advocate for talent recruitment and development. He consistently strives to understand the aspirations of his team members and proactively shapes opportunities that allow colleagues to navigate new dimensions of professional growth. A testament to his success is the outstanding composition of scientists with diverse skill sets and backgrounds who possess the ability to tackle a vast array of scientific challenges in drug discovery.

Getting to know...

Murray McKinnon, Ph.D.

TITLE: VP, Head of Immunology Discovery & Janssen Immunosciences

COMPANY: Janssen Research & Development LLC, one of the Janssen Pharmaceutical companies of Johnson & Johnson

EDUCATION: BSc, Biochemistry, University of Glasgow; Ph.D., Biochemistry, Imperial Cancer Research Fund, London, UK

FAMILY: Wife, parents, children

HOBBIES: Golf, photography, travel

BUCKET LIST: Visit the Great Wall of China; learn to speak Spanish; go fishing in Alaska, photograph the Northern Lights

Dr. McKinnon is very well connected across the industry and as a strategic leader he is always thinking of the next challenge and planning ahead, and helping his team to do the same. He can aptly lead internal and external alliances, maintaining a professional but personable relationship with partners and keeping the scientific data foremost in driving decisions.

While maintaining his leadership of Immunology Discovery at Janssen, Dr. McKinnon will soon be steering a new path to bring new immune-oncology concepts to the clinic through the recently formed Janssen Immunosciences Center of Excellence. Company leadership anticipates a significant impact with Dr. McKinnon in this new leadership role.

"The field of immunology continues to emerge as a key underlying component of many important diseases, not only autoimmune diseases, but also areas including, oncology, metabolism, neuroscience, and virology," Dr. McKinnon says. "My goals are to continue to leverage the immunology capabilities we have built at Janssen to support the entire disease area portfolio and to deliver innovative new approaches to targeting immune-mediated diseases."

According to colleagues, Dr. McKinnon exemplifies the highest qualities of a leader for a drug discovery organization. He has developed and led one of the most competitive discovery immunology groups in the pharmaceutical industry based on his prescient ability to identify future innovation needs and the skill sets to successfully tackle emerging areas of science.

In the future, he would like to see team-building beyond the walls of J&J and more collaboration between industry and academia that allows for sharing of data, resources, compounds, and brainpower.

"Our challenges are significant and we need to bring the best and brightest minds together to tackle new and existing diseases," Dr. McKinnon says. PV

Driven to innovate by PATIENT NEEDS