

MARK PENNISTON

The Curious Pragmatist

n this biotech environment, it's rare to find teams that stay together for decades. But when you have a team led by folks like Mark Penniston, executive VP of clinical analytics at Chiltern, every day is different

from the previous. His inherently varied way of tackling the next challenge inspires and encourages his teams.

With a statistical, computing, and molecular biology background, he is applying his unique vision for how a data sciences group should be orchestrated. Taking skills learned from his experience with big pharma and contract research organizations, he took the helm of a business unit that is blurring the lines between CRO, business processing outsourcing, and technology leadership at Chiltern.

Mr. Penniston leads a team of global professionals in clinical data analytics, data management, biometrics, and statistical programming and CDISC solutions, as well as Chiltern's statistical research center. In the last 20 years, he has served in positions of increasing responsibility in global clinical data management, biometrics, and clinical writing.

While other companies implemented their own versions of technology, Mr. Penniston sought to leverage the best technology the industry offers to deliver incredible solutions. His willingness to significantly invest in training teams to work across multiple platforms in ways that align best with the customers needs allowed for rampant growth — which drew some of the industry's best talent to join him. Without any formal acquisitions, Mr. Penniston's clinical analytics group has gone from 300 to 1,600 team members in less than 10 years deployed across four continents.

Colleagues say the clinical analytics group, despite its size, reach, and customer base, still has a familial feel. And this year, once again, the company is celebrating more employees with 20 years of service to Chiltern.

Mr. Penniston says when he was younger, he would have said a career highlight was to see the successful approval of submitted drugs that he worked on.

"As I grow older, it has been how to help multiple groups ease their product research



Taking skills learned from his experience with big pharma and contract research organizations, Mark Penniston took the helm of a business unit that is busily blurring the lines between CRO, business processing outsourcing, and technology leadership at Chiltern.

and approval processes," he says. "From a measure of success, together with people I work with we have helped build growth rates of more than 20% year to year."

He says his current goals include addressing patients' needs by getting products through the process quicker and safer by automating the tedious work of clinical trials. Forever the analyst, he says tongue in cheek that success is measured by growth of good and reduction of bad.

Mr. Penniston says his most challenging assignment was during the recession when he was tasked with telling staff there was not enough business to keep them employed.

"These were good people and the company let them down," he says. "This motivated our team to not have to perform that again. We built our clinical analytics business up on the premise of not letting your fate be dependent

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He believes the adoption of data standards will lead to big changes in healthcare.

"I'm looking forward to when I can walk into any doctor's office and my entire medical history is available for a clinical trial when necessary," Mr. Penniston says. "But somehow, we have to bridge the gap of patient confidentiality to access of information. Finding patients, patient enrollment, and access to data continue to be major delays in determining product efficacy."

Fostering innovation, however, requires a culture where good enough is not acceptable. He says organizations constrain innovation when they place people into positions of responsibility who do not want to listen about improvements that can be made or when there is the sense of lack of fairness.

"This can really cause a challenge to an organization's ability to innovate," he says. "Technology and/or people will continuously drive improvement when given the opportu-

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ETIENNE DROUET

Where Science and Data Intersect

ith a passion for unraveling and translating complex data into carefully crafted operational solutions, Etienne Drouet aims to improve clinical trials. For two-plus decades, he has focused on understanding the clues that complex trial data reveal through careful analysis to power more strategic development of cancer treatments. He started his journey as a research scientist at a biotechnology company and has moved into increasingly more responsible roles supporting oncology clinical trials.

As VP, strategic development, at Synter-actHCR, Mr. Drouet drives oncology clinical development strategy to meet client and operational objectives by leveraging his decades of experience in the field. He provides executive oversight by interacting with the client and the delivery teams on oncology projects to ensure high-quality project deliverables and client satisfaction.

Mr. Drouet has had a great impact on numerous drug developments and, as a result, contributed greatly to the benefit of patients. He brings extensive knowledge in organizational logistics and its impact on clinical trials, as well as a strong analytical approach to the data being generated, proactively identifying potential pitfalls, factors influencing the effective execution of trials, and lessons that can be learned.

An accomplished leader who is inclusive and fair-minded, Mr. Drouet supports cross-functional teams with knowledge and patience in explaining complicated concepts in rapidly evolving areas of science and research.

He has been instrumental in supporting project teams on multiple occasions, providing guidance, inspiration, and support at Getting to know...

Etienne Drouet

TITLE: VP, Strategic Development

COMPANY: SynteractHCR

EDUCATION: Biotechnology Engineer, Ecole Superieure de Biotechnologie de Strasbourg; MS, Molecular and Cell Biology, University Louis Pasteur

FAMILY: Wife

HOBBIES: Hiking, history, politics

BUCKET LIST: Spend more time with family

SOCIAL MEDIA: in

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high levels, specifically providing valuable client feedback on protocol study design and using his expertise to help map out complex enrollment timelines that have really helped align expectations on how to best move studies forward while being realistic about enrollment in rare disease indications.

"I am most excited when I am working to find a solution where science and data intersect," he says. "I love to solve operational issues in clinical research by understanding the complexities of the science and applying that understanding to resolve problems that could impact the viability of these important, possibly life-altering studies."

Since joining SynteractHCR in early 2015, Mr. Drouet has been invaluable to key stake-

ANALYTICAL. STRONG WORK ETHIC.



Etienne Drouet's style is to provide data-based evidence to suggest improved approaches to clinical trials.

holders inside and outside the company by leveraging medical and operational experience and analyzing current information and case studies, to glean insights and predictions on new or often ongoing projects. He says his career highlight has been taking the global leadership of the oncology portfolio and strategic development group.

He is a big proponent of analyzing data to uncover findings often overlooked, the result is that he's able to validate, and/or disprove hypotheses, as well as get at the root cause of issues others might miss.

"Before acting, my first approach is to make an analysis of the situation," he says. "I take some distance to get a broad picture and at the same time paying attention to details. I normally make a decision on the action to take only after an analysis and evaluation of the action's impact on the situation."

Mr. Drouet is highly valued as a leader by his peers, by customers, and the research community. He is supportive and open to new technologies and approaches and encourages others to pursue their own passions and ideas. Colleagues say when you meet him, you know instantly that he truly cares and is inspired by the work that he does.

He says he is motivated to go to work every day to look for information and learn to share this knowledge with others.

Knowledgeable

Inspirational

Vigilant Analytical Dedicated Bright

Mentor

Engaged

Client-Focused

These are all qualities we associate with a PharmaVoice 100 winner..... especially Etienne Drouet, our Vice President of Strategic Development. We celebrate your efforts to bring tomorrow's treatments to patients in need.

Congratulations to you, Etienne, and all the 2017 PharmaVoice 100 winners who exemplify the best of the best in our industry.





Getting to know...

Howard Mayer, M.D.

TITLE: Senior VP, Global Head of Clinical Development

COMPANY: Shire Pharmaceuticals EDUCATION: BA, Biology/Psychology,

University of Pennsylvania; MD, Albert Einstein

College of Medicine

FAMILY: His wonderful and incredibly supportive wife Mara; two children, Jordan and Aubrey, who have changed his outlook on life

HOBBIES: Cooking, crossword puzzles, guitar, gardening

BUCKET LIST: See Led Zeppelin live in concert (if they ever tour again)

he underlying mantra of Howard Mayer, M.D.'s work is: set the bar high and then surpass it. As senior VP, head of global clinical development at Shire Pharmaceuticals, Dr. Mayer is responsible for global clinical development across all of the company's therapeutic areas, including hematology, immunology, oncology, genetic diseases, gastrointestinal/metabolic, neuroscience, and ophthalmology. In total, Dr. Mayer oversees nearly 40 programs in the clinic with more than 20 in the later stages of development, many with a significant focus on areas of high unmet medical need and rare disease patient populations.

His most recent successes include the 2015 approval of Vyvanse for the treatment of binge eating disorder — making it the first FDA-approved medication to treat this condition — and the 2016 approval of Xiidra for the treatment of dry eye disease.

Dr. Mayer says he is driven to find new medicines for patients with rare diseases. His motivation is the opportunity to focus on therapies that can have the most profound impact on patients and to make a meaningful difference in the lives of people fighting rare diseases and highly specialized conditions.

Dr. Mayer is a recognized leader and a respected clinical expert whose dedication, personal passion, and drive set an example for those who work alongside him. Colleagues say he is a truly inspirational leader who is a standout scientist and role model for the industry.

But even with extensive training and deep

DR. HOWARD MAYER

A Dedicated Clinical Expert

DRIVEN. AUTHENTIC.



Dr. Howard Mayer has an ability to envision a better tomorrow and take the necessary steps today to make that future a reality.

Driven to collaborate by

expertise in clinical development, which allows him to contribute across many therapeutic areas, Dr. Mayer is a true scientist at heart and he brings an innovative spirit to his work every day. He is open to new ideas, encourages debate, and welcomes constructive challenges, knowing that the best solutions rarely stem from one individual but instead are a result of collaboration and ultimately benefit patients.

Dr. Mayer's belief in the power and strength of a team may be why he chooses to avoid the limelight, even as a highly accomplished individual in his own right. By

prioritizing "we" above "I," Dr. Mayer sets a commendable example for those around him. And despite his humility — or perhaps because of it - Dr. Mayer's influence extends well beyond his immediate team and spans the company.

His work ethic and high degree of professionalism are widely recognized and valued by individuals from various groups within Shire, underscoring his ability to bring colleagues together while also delivering results with minimal distractions, knowing the all-important role of clinical development as Shire strives to bring transformative treatments to millions of patients around the world.

These accomplishments prompted Shire's executive committee, led by CEO Flemming Ornskov, to honor Dr. Mayer with a special CEO award to acknowledge his steadfast focus on leadership and success on behalf of patients since joining Shire in 2012.

It is no surprise that Dr. Mayer's achievements have distinguished him in the broader industry as well. In early March, he was appointed to the board of directors of Genocea Biosciences, where his expertise will help the company advance its clinical programs. He also serves on the scientific advisory boards of Macrolide Pharmaceuticals and Arsanis Biosciences.

Dr. Mayer's leadership brings a unique perspective to Shire's clinical development programs, and inspires team members to come to work with a shared sense of purpose — to help patients. His ability to envision a better tomorrow and take the necessary steps today to make that future a reality put him among the leaders both at Shire and within the industry at large.

Outside of work, Dr. Mayer's favorite charities are Melmark New England and Autism Speaks. He has served on the board of Autism Speaks in New England since 2011 and on the board of the Melmark Charitable Foundation since 2016. **2**

PASSIONATE. DETERMINED.



aulo Moreira is a committed advocate for patients and for their critical participation in the clinical trial enterprise. As VP, global clinical operations, external innovation at EMD Serono, he continually challenges the status quo, bringing in the voice and needs of patients and investigators and systematizing best practice so that it can scale effectively. He believes the whole is greater than the sum of its parts, which is why he his committed to collaborating with the different stakeholders.

Mr. Moreira has been a thought leader and driver of patient-centricity in clinical development for years. He has led and implemented initiatives at EMD Serono where patient input is successfully sought and considered appropriately across clinical development, impacting investment and development decisions that have a considerable and positive impact on

He says one of his goals is to increase the global percentage of patients who volunteer to participate in clinical trials by at least 1%.

"This seemingly small number translates into enormous improvements in the speed of drug development," he says.

Other goals include helping to put new medicines on the market that will make a difference in people's lives, to eradicate at least one form of cancer, and to continuously make rare diseases even rarer.

He believes the industry needs to collectively create an environment that attracts patients and caregivers to participate in clinical

He wants to be remembered for the pioneer work he has done in ensuring that patients have an opportunity and a say in how drugs

Driven to collaborate by

are developed, as well as ensuring that patients who participate in clinical trials receive the recognition they deserve for their role in the advancement of medical science.

Mr. Moreira's passion for improving the patient experience and accelerating medicine development led him to participate in Trans-Celerate, where he leads an initiative that is examining how to enhance clinical research awareness and access, the goal of which will be to help impart best practices across the entire medicine development industry.

Colleagues say Mr. Moreira not only develops great strategies but also engages colleagues and peers equally, effectively sharing inventive approaches. His role as leader in the pharmaceutical industry is additionally underlined in his function as mentor. He enjoys passing on skills, expertise and experiences to junior colleagues. As a mentor with the Healthcare Businesswomen's Association, he has been a great supporter for junior women in the healthcare industry.

Leadership, he says, is not prescriptive, but descriptive, and it can be summarized as being one within the team as opposed to being in front of the team. He says he aims to inspire people through his "life and leadership" paradigm.

"It starts with live your life with purpose," he says. "Love what you do and do it with passion. Laugh often. Lend your time, your expertise and your resources to those in greater need than you. Lead the way; don't wait. LisGetting to know...

Paulo Moreira

TITLE: VP, Global Clinical Operations - External Innovation

COMPANY: EMD Serono Inc.

EDUCATION: BS, Salve Regina University FAMILY: Wife, Margaret; children, Michael, 17;

HOBBIES: Coaching youth soccer at Elite Level for East Bay United in RI

remaining; write a book; patent an invention AWARDS/HONORS: PharmaVOICE 100 2015. 2017; President's Award; LEAD Award for providing development opportunities for others; Value Awards, several for integrity and achievement

BUCKET LIST: Visit all 50 States — eight

ASSOCIATIONS: Clinical Trial Transformation Initiative (CTTI); Society for Clinical Research Sites (SCRS); Drug Information Association (DIA); Linking Leaders, Healthcare Businesswomen's Association

SOCIAL MEDIA: i 🔀 😉

TWEET AT: @pauloImoreira





ten and pay attention to others and to what goes on around you. It concludes with legacy, which has to do with perseverance and having

an impact in everything that you do."

"In the 2015 PharmaVOICE 100, I introduced my 'Ls' of life and leadership," he adds. "I live every day of my life with a few simple rules. Over time, I have added a couple more dimensions to this paradigm. The two new additions are labor, which signifies that hard work is needed to make things happen and to overcome adversities. And learn closes the list as a reminder to stay humble. There are always people smarter than me in the room who can teach me a great deal."

He says he wouldn't do anything different

"The mistakes, I have made, the challenges and adversities I have had to overcome have taught me invaluable lessons that otherwise I would not have learned," he says.