**Beating disease with systems approaches and big data**

*The pharmaceutical sciences are heading for a future that could combat disease with individual, tailored treatments. Systems therapeutics is making this a reality. Experts and stakeholders from all fields of pharmaceutical science need to work together to harness data, and bring the right medicines to the right patients.*

By Alice Rolandini Jensen

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“There are many diseases that we can manage, but by understanding how disease works on a molecular level throughout the organism, we might have the chance to cure those diseases,” says Giovanni Pauletti, Associate Professor of Biopharmaceutics & Pharmacokinetics at the University of Cincinnati, USA. The human body is a complex interconnected system. Isolated from one another, organs do not function as they should, nor do the cells that organs are comprised of, or the biomolecules acting within and between them. Intricate connections between molecules, cells and organs act like an underlying blueprint for life that we are yet to fully understand. Systems therapeutics aims to uncover the secrets of this blueprint and shape the future of medicine.

Based on the principles of the emerging field of systems biology, systems therapeutics is creating unprecedented opportunities to develop novel medicines. We will see personalised medicine, with respect to both the selection of medicines and dosing regimens. Treatments will be disease modifying and both pre-emptive and preventive. They will also be complex, and we will see multi-target drugs, rational drug-drug combinations and drug-device combinations. All those involved in the pharmaceutical sciences, from researchers in academia and industry, to regulators, policy makers and clinicians, will meet to discuss this exciting future at the 6th Pharmaceutical Sciences World Congress 2017 (PSWC 2017) that will be held by the International Pharmaceutical Federation (FIP). The gathering will see experts discuss the central theme “Systems approaches to drug discovery, development and clinical usage.”

**Holistic approach**

“Systems approaches to pharmaceutical science is a modern holistic approach,” explains Dr Pauletti, who is also FIP’s Scientific Secretary. “Here, we focus on the entire organism, not only the part of the body affected by disease. By understanding the interconnectivity between systems, we can now optimise medicines therapy to result in greater benefits for the individual patient. Specifically, we can tailor an individual’s treatment so that a medicine is more effective and has less side effects.”

Key to the advent and implementation of systems approaches are the technological advances that are enabling researchers to create accurate models of the body systems and medicine interaction. “In 2014, the Nobel Prize in Chemistry was awarded for the development of high resolution microscopy. Now, we are using these prize-winning techniques together with other state-of-the-art strategies, such as high resolution mass spectrometry, to visualise and quantify compounds within cells,” says Per Artursson, Professor in Dosage Form Design at Uppsala University, Sweden, and leader of the PSWC 2017 track on drug delivery and targeting sciences. “In their most advanced set ups, these technologies allow us to look inside organs, and even into cells, to see exactly where a medicine distributes. We can now see how medicines interact with almost all proteins in a cell and understand potential effects and side effects.”

**More data than ever**

Emerging technologies are providing pharmaceutical researchers with more data than ever before. Analysis of this “big data” is what is really driving the success of computer models. “Not only are there a lot of data, there are a lot of different types of data that need to be put together,” explains Kathy Giacomini, Co-director of the University of California at San Francisco - Stanford Center of Excellence in Regulatory Sciences and Innovation and leader of the PSWC 2017 track on drug design, fundamental and translational sciences. “We collect data from patients taking various medicines. Our team and others integrate these multiple datasets to produce computer models and predict drug level or drug response in an organ, or a whole organism. These models must be validated before they can be used to inform drug discovery, design, development, therapeutic use, etc.”

Professor Artursson adds, “Sciences have developed technologies called -omics, that create a lot of data and parameters. So now, we can determine the quantities of all proteins in a cell, all transcripts in a cell, and all metabolites in a cell. When you gather this information, and how it changes when you get a disease or add a drug, we get a completely different view of what is happening in a cell and in an organism.” Quantitative -omics data also provide essential information for improved modelling of disease and drug effects.

Despite the effectiveness of models, we must remember that, no two patients are the same. All those involved in the pharmaceutical sciences are developing systems therapeutics to pave the way for individualised therapies that consider the specific needs of a patient. Professor Giacomini’s expertise lies in genomics and she gives an example of how this can come into play: “Ivacaftor was developed to treat those with cystic fibrosis. But, it was developed for patients with a specific genotype which led to questions over how to ensure effective use in patients. Should patients with other genotypes, but no medicines available to them, also be allowed to take the medicine? And how do clinicians implement the genetic testing and ensure medicines are administered correctly?”

Professor Giacomini’s questions highlight the importance of ensuring interconnectivity between those involved in research, and those who make the decisions that lead to treatment of patients. The PSWC 2017, to be held in Stockholm, Sweden, from 21 to 24 May 2017, provides a unique and rare chance for all pharmaceutical stakeholders to exchange most recent research findings and form alliances and networks that will improve patient outcomes in the future. One of the special highlights of this international get-together is the Young Scientist Satellite Conference (19–21 May) emphasising the need to develop young researchers as the pharmaceutical scientists of tomorrow. Giving future experts the skills and knowledge to realise the potential of systems therapeutics is key if we are to see the success and widespread application of tailored and individualised therapies.

[www.fip.org/pswc2017](http://www.fip.org/pswc2017)