A brief report of the conference : 6th FIP Pharmaceutical Sciences World Congress (PSWC) held at Stockholmsmässan,Mässvägen 1 Älvsjö 125 80 Stockholm , Sweden on 21-24 May 2017

- Vandana Arora Sethi, Director, Lloyd Institute of Management & Technology

The highlights of the event were :

- Met and networked with key opinion leaders in pharmaceutical sciences from all over the world
- Learnt what will happen in the future from leading experts
- Heard high level speakers share their latest research in plenary sessions, workshops, debates, roundtables and unique regional showcases

I could get insights into the following areas:

- **New scientific disciplines** "Systems pharmacology" , focusing on the medicines-genetics interface and on biological network analysis as the scientific basis for drug action. This will enable efficacy and safety decisions, and will involve the development of novel concepts, biological models and biomarkers practice and we will be able to use "big data" for post-marketing drug evaluation. Systems therapeutics will trigger important discussions of the societal aspects of pre-emptive and preventive treatments.
- **More information, improved safety** In translational sciences, systems pharmacology models will cast light on pharmacokinetics and pharmacodynamics. This will fuel the optimisation of clinical trials in healthy subjects, patients, special populations and real-life populations. Similarly, systems toxicology models will be used for toxicity and safety evaluations in drug development.
- **Precision treatments** Systems therapeutic interventions are "precision treatments" that are tailored to individual patient characteristics, both with respect to drug choice and dosing regimen. They will change the field of formulation and manufacturing sciences. Interventions that require precise individualised dosing will impact on pharmaceutical

formulation and processing. We will need to design new diagnostic tools and monitoring devices.

- **Harnessing of "big" information** In regulatory science, the systems approach will allow advanced modelling and simulation that will be used to enhance product safety and to improve the prediction from clinical evaluations. We will be able to harness diverse data through information sciences to improve health outcomes.
- **Science-based practice** The practice of science-based pharmacy will see major change. Individualised treatments will be a significant part of clinical practice and we will be able to use "big data" for post-marketing drug evaluation. Systems therapeutics will trigger important discussions of the societal aspects of pre-emptive and preventive treatments.

<u>The report of the 4 day event is as follows</u>:

21st May 2017

Plenary Opening Ceremony :*Future Medicines for One World'* Welcome reception

Introduction to the theme of the conference: Future Medicines for One World

1. Medicines for One World through global collaboration and harmonization
Dan Hartman / Bill & Melinda Gates Foundation, USA
2. Systems Biology – from symptomatic relief to disease modification and cure
Hiroaki Kitano / Systems Biology Institute, Japan
3. Open Innovation – strengthening research, enhancing transparency & attaining public support
Pierre Meulien / Innovative Medicines Initiative, Belgium
4. Cultural contribution

22nd May 2017

Plenary Opening Symposium

1. Introductory remarks
Hiroshi Suzuki / University of Tokyo, Japan
2. Future medicines: fundamental and translational sciences
Richard Bergstrom / EFPIA, Belgium
3. Future medicines: drug delivery & targeting sciences
Kazunori Kataoka / University of Tokyo, Japan
4. Future medicines: formulation, manufacturing and quality assurance
Jukka Rantanen / University of Copenhagen, Denmark
5. Future medicines: regulatory sciences
Tomas Salmonson / MPA, Uppsala Sweden & EMA, London
6.The science of precision medicine and its trans-lation to the clinic
William Evans / St Jude's Children Research Hospital, USA
7. The emerging discipline of Quantitative Systems Pharmacology (QSP): combining PKPD and Systems Biology : This session brought together a world-class group of scientists focussing on the interfacing of quantitative systems pharmacology (QSP) and Systems Biology (SB) with the aim to understand the interactions between drug action and disease processes. QSP

constitutes the scientific basis for the design of novel disease treatments which modify the disease process.

- The emerging discipline of Quantitative Systems Pharmacology (QSP): combining PKPD and Systems Biology : *Piet van der Graaf / Leiden University, The Netherlands*
- Quantitative systems pharmacology in oncology: *Don Mager / University at Buffalo, USA*
- Quantitative systems pharmacology in infectious diseases : *Alan Perlsson / University of New Mexico, USA*
- Quantitative systems toxicology :*Hiroshi Suzuki / Tokyo University, Japan*
- Systems medicine in rheumatoid arthritis : *Tim Radstake / UMC Utrecht, The Netherlands*

8. Lectures towards understanding compound disposition at ever higher spatial resolution by label free methods This session focussed on contemporary methods for increasing the understanding of cellular and subcellular compound disposition using unlabelled drugs, suitable for use in the lead optimisation phase.

- Intracellular unbound drug concentrations: methodology and application for understanding cellular drug exposure: *André Mateus / University of Uppsala, Sweden*
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- A modular probe strategy for drug localization, target identification and target occupancy measurement on single cell level : *Anna Rutkoswka-Klute / Cellzome, Germany*
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- 3D label-free imaging of drug uptake into cells and bacteria using secondary ion mass spectrometry : *Paulina Rakowska / National Physical Laboratory, UK*

9. Innovative Production Technologies for Biologics
The need for high quality biologic drugs, including biosimilars, is fueling innovation in biopharmaceu-tical manufacturing technologies. This symposium outlined opportunities and challenges associated with new technologies such as single-use bioreactors, continuous purification processing, and real-time quality analysis that have been effectively explored to enable fast scale-up of high-quality complex products.

- Innovation in biologics drug product development & manufacture :*Hanns-Christian Mahler / Lonza, Switzerland*
- Quality risk management in the manufacture of biologics : *Akhiko Hirose / National Institute of Health Sciences, Japan*
- Control strategies for surfactants in biopharma-ceuticals: *Atanas Koulov / Lonza, Switzerland*
- Centralized end-to-end biologics repository and analysis platform: *Peter Henstock / Pfizer, USA*

10. New approaches of regulating innovative medicines
Throughout the world, regulators are exploring new ways to provide access to patients for innovative medicines that address urgent medical needs at the earliest moment, while assuring appropriate controls for quality, safety and efficacy. In this session it assessed current approaches in different regulatory systems, explore commonalities and identifies lessons for the future: *Alasdair Breckenridge / University of Liverpool, UK*

11. Clinical implementation of precision medicine: from genomewide discovery to practice
With recent initiatives in the USA and indeed globally, precision medicine represents a new discipline specifically focused on the translation of genomic discoveries to patient care. However for precision medicine to become a reality major challenges must be addressed. First and foremost, large cohorts of patients with available biological samples and electronic health information are needed to make robust discoveries that can be effectively translated to patient care. Importantly, expert advice on the use of genomic information to guide drug selection and dosing in the context of individual patients from diverse ethnic and racial backgrounds is needed.
This symposium focussed on key issues for implementation of precision medicine in patient practice. Issues relevant to translation of new discoveries were highlighted, particularly, the use of genetic information to guide the selection of safe and effective therapies.
Kathy Giacomini / University of California, USA

23rd May 2017

Systems approaches to modeling the contribution of transporters in drug disposition, response and toxicity

This session brought together a world-class group of scientists who gave a range of presentations that focussed on experimental and computational models to understand the role of drug transporters in drug toxicity and response with a particular focus on the blood brain barrier.

- Systems approaches to modeling the contribution of transporters in drug disposition, response and toxicity – general introduction *Mikko Niemi / University of Helsinki, Finland*
- Quantifying the impact of transporters on cellular drug permeability *Per Artursson / University of Uppsala, Sweden*
- Modeling and prediction of the effect of transpor-ters on differences of unbound drug concentrations between the plasma, brain and cerebrospinal fluid *Yuichi Sugiyama / University of Tokyo, Japan*
- Organic action uptake of cocaine, other opioids, and cathinones at the BBB *Jean-Michele Scherrmann / Paris Descartes University, France*
- Organic action uptake of GHB at the BBB: incorpo-ration of brain transport in modeling of PK/PD *Marilyn Morris / University at Buffalo, USA*
- Systems approaches to modeling the contribution of transporters in drug disposition, response and toxicity – concluding remarks *Rada Savic / University of California, USA*
- Drug targeting: principles and products for precision medicine: Many drug delivery systems and drug targeting strategies have been evaluated over the years. In this session, recent advances in the use of targeted (nano-) therapeutics for improving the treatment of cancer, cardiovascular disease and inflammatory disorders were presented. In this context, both fundamental insights into biological and pathophysiological mechanisms, as well as progress towards pharmaceutical production and clinical translation were addressed.
    - Drug targeting to tumors: Concepts and barriers vs. ever more nanocarriers: *Twan Lammers / RWTH Aachen University Clinic, Germany*
    - Harnessing RNA nanomedicine for precision therapy in cancer and inflammation: *Dan Peer / Tel Aviv University, Israel*
    - Drug targeting and imaging in cardiovascular disease :M*illem Mulder / Mount Sinai School of Medicine, USA*
    - Bioresponsive polymeric nanomedicines for tumor targeting: *Zhiyuan Zhong / Soochow University, China*

8. Continuous manufacturing – As conventional large batch manufacturing is increasingly regarded as inflexible and unsustaina-ble, the continuous manufacturing concept has planted a new hope in the pharmaceutical industry to improve process efficiency and product quality. This session highlighted the various elements necessary for successful implementation of continuous manufacturing predicted to resulting in reduced production time and a shorter time to market.
    - Continuous manufacturing: the future in pharma-ceutical solid dosage form manufacturing: *Paul Wan Sia Heng / National University of Singapore, Singapore*
    - Making the business case for continuous manufac-turing in the pharmaceutical industry : *Tomás Harrington / University of Cambridge, UK*

- Developing the end-to-end supply chain: *Craig Johnston / University of Strathclyde, UK*
- On-demand continuous-flow production of pharmaceuticals in a compact, reconfigurable system: *Andrea Adamo / MIT, USA*
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- Manufacturing concepts for individualised therapies

  Recent breakthroughs in diagnostics, including genotyping and biomarkers, have paved the way towards implementation of 'precision medicine' intended to meet the therapeutic needs of each individual patient. To fully achieve societal benefits of individualised therapies, conventional manufacturing platforms must be adapted for mass customization. This session focussed on the challenges and opportunities associated with enabling future mass customized formulation and manufacturing technologies needed for precision pharmaceutics.

  - Introduction to manufacturing concepts for individualized therapies – where are we in pharma :*Staffan Folestad / AstraZeneca, Sweden*
  - Additive manufacturing of individualised medicines: *Niklas Sandler / Åbo Akademi University, Finland*
  - Nano-engineered drug delivery for individualised therapies : *Paula Hammond / MIT, USA*
  - Innovative developments in patient centric formulations : *Alvaro Goyanes / UCL, UK*

10. Education & training of the future pharmaceutical sciences workforce

Development of novel medicines capable of more effectively reducing disease burden across the globe challenges existing paradigms of pharma-ceutical sciences education and training. This session outlined the opportuni-ties for academia and industry working jointly on innovative training programs to foster a compe-tent pharmaceutical sciences workforce that is ready to tackle the challenges of the future. In addition to presentations from pharmaceutical sciences educators and employers, this session featured viewpoints from young pharmaceutical scientists (i.e., graduate students, postdocs, new employees) and a moderated interactive panel discussion engaging the members of the audience with speakers.

- Opportunities for the future pharmaceutical sciences workforce: *Giovanni Pauletti / FIP, USA*
- Attracting the best students into a pharmaceutical sciences career : *Case studies of young pharmaceutical scientists from different geographical regions who entered PharmSci from non-traditional background*
- Tomorrow's pharmaceutical sciences workforce – employer perspective: *Brian Henry / Pfizer Worldwide Research and Development, UK*
- Innovative models of PhD training: *Ross McKinnon / Flinders University, Australia*

24th May 2017

1. Use of 'Extended Clearance Concept' in new drug discovery and developement; application to a drug classificati-on system and to a design of clinical studies: *Yuichi Sugiyama /University of Tokyo, Japan*
2. Adherence, in drug development and usage: *Bert Leufkens /Utrecht University, The Netherlands*

3. Systems pharmacology – innovative approaches to drug safety. This session discussed : how *i)* drug safety predictions based on pre-clinical studies can be exploited to inform clinical safety predictions; *ii)* information from post-marketing adverse event databanks can be utilized to inform drug safety; *iii)* systems pharmacology approaches can complement big data analysis to understand the underlying molecular and mechanistic causes of adverse events for hypothesis generation and novel safety predictions.
    - Regulatory perspective on drug safety assessment during drug development :*Masanobu Sato / Pharmaceuticals and Medical Devices Agency (PMDA), Japan*
    - Application of systems pharmacology modeling to explore safety issues arising at different stages of drug development: *Oleg Demin / ISB Moscow, Russia*
    - Translating preclinical safety signals to the clinic to inform compound discovery and early development : *Jay Mettetal / AstraZeneca, USA*
    - Systems pharmacology models to assess immuno-genicity : *Paolo Vicini / MedImmune, UK*
    - Integration of mechanistic information generated through systems pharmacology into pharmaco-epidemiologic studies aimed at making inferences about the real-life impact of emerging safety concerns*Almut Winterstein / University of Florida, USA*
    - Patient data driven strategies in drug safety assessment : *David Jackson / Molecular Health, Germany*

4. Oral absorption of biopharmaceuticals revisitedOral administration is the preferred route of administration for drugs but this route has not been feasible for biopharmaceuticals due very poor absorption due to the large molecular weight, hydrophilic nature and instability to enzymatic degradation in the gastro-intestinal (GI) tract. Attempts have therefore been made for more than 30 years to develop drug delivery systems allowing to overcome these obstacles and make oral products possible. Unfortunately, the outcome has been disappointing and today there are still no oral biopharmaceutical drug delivery based products for systemic treatment on the market. However, there is a currently a renewed research interest in this challenging field. One of the factors that changed the game is chemistry progress providing stable modifications thereby both avoiding GI degradation as well as generating very slow systemic elimination. The latter aspect is impor-tant from a drug delivery perspective since the fluctuations in plasma concentrations will be less sensitive to variations in extent of absorption at steady state. Thus, this re-opens interest for delivery approaches that enhances oral absorption of such drugs. Today this approach not only includes peptides but also small oligonucleotides further boosting interest. This session gave a timely update of recent advances in this field and stimulate a discussion of remain critical questions and next steps: *Hans Lennernäs / Uppsala University, Sweden*

5. Big data, real world evidence and regulatory science
   In recent years, progress in the collection, storage and analysis of real-world data has opened up promising avenues for pharmaceutical innovation. The challenge for the pharmaceutical sciences will be to harness this potential and utilize it to explore new treatment strategies and gather valuable evidence on the safety and effects of medicines in clinical practice. This session discussed the current state and ways forward: D*arieke De Bruin / University of Copenhagen, Denmark*54 55