Programme

Introduction to Anton Paar

Seminar by
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S4A Level 3 Seminar Rooms A&B
NUS Department of Pharmacy

Thursday, 28 November 2019
2 - 3.30 pm

All ARE WELCOME
Research Seminar

Follow-on nanomedicines: identical twins or distant cousins?

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Abstract

The application of nanotechnology to the development of advanced therapeutics has brought about a number of so-called “nanomedicines”. Such drugs, though showing high variability in terms of size, shape, materials used, etc. share complex structures, which cannot be characterized in their entirety. Being mostly of synthetic origin and their preparation often including a self-assembly step, such drugs are referred to as non-biological complex drugs (NBCDs). Their size and attributes at the molecular scale confer these systems certain properties that impact their interaction with their biological environment, and thus influence PK/PD and safety profiles.

FDA called for an improved review process of generic drug applications (ANDAs). This must be viewed in relation to nanomedicines, as well, as several follow-on products have entered the market. FDA has also issued a guidance draft on products containing nanomaterials. Even though this draft guidance is suggesting a list of properties of nanomedicines (“Nanomaterial Quality Attributes”) to be tested, it lacks true guidance on individual (groups of) nanomedicines. It presumes levels of knowledge of product behavior that are typically not available, neither for NDA nor for generic, ANDA products.

Due to their inherent complex structure, nanomedicines are impossible to be fully characterized by physicochemical methods alone, in vitro as well as in vivo studies, leading up to verification in clinical trials, are required. Therefore, an effort is needed to discover these correlations between specific critical quality attributes (CQA) and their impact on biological activity, ideally to be able to predict in vivo behavior. This can only be realized through a multi-pronged analytical approach and correlation to clinical data. In addition, follow-on products, so called nanosimilars, are entering the market through the generic pathway. Although studies showed that these products do have a different efficacy and safety profile than the originator product, they are deemed to be interchangeable in clinical practice.

This presentation will discuss the current state of identification of CQAs using examples from currently marketed nanomedicines.

Biography

Gerrit Borchard is a licensed pharmacist and obtained his Ph.D. in pharmaceutical technology. After holding several academic positions at Saarland University (Germany) and at Leiden University (The Netherlands), he joined Enzon Pharmaceuticals, Inc. (USA) as Vice President Research. In 2005, he was appointed Full Professor of Biopharmaceutics at the University of Geneva (Switzerland), and in 2015, he was an invited professor at Graz University (Austria).

Prof. Borchard has published more than 140 scientific papers (9121 citations, h-factor 50) and 23 book chapters, he edited two books, and is named as inventor on 10 patents. Since 2014, he is president of the Swiss Academy of Pharmaceutical Sciences (SAPhS). In 2012 he joined the Non Biological Complex Drugs (NBCD) working group hosted at Lygature (Utrecht, The Netherlands), joining its steering committee in 2015. He was nominated Chair of the NBCD working party at the European Directorate for the Quality of Medicines & Health Care (EDQM) by Swissmedic, and joined the External Advisory board of the EU-Nanotechnology Characterization Laboratory (EU-NCL) in 2016. He was appointed to the steering board of contactpointnano.ch, a platform fostering SMEs in the field of nanomedicine, in January 2019.

Due to his working in both academia and industry, and living in four countries, Prof. Borchard has acquired extensive experience in diverse working and cultural environments, and is fluent in Dutch, English, French and German (native). Being an enthusiastic long-distance runner and triathlete, he loves to roam the trails and by-roads of the Jura mountains on foot and bike.