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Keynote Forum

Day 1

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Advanced Therapy Medicinal Products (ATMPs) in the light of precision (personalized) medicine

Precision medicine is expected to lead to a paradigm shift in treatment approach. Scientific and technological advances lead to another type of medicinal product: precision medicine is targeted ('personalized') medicine, as opposed to small molecule one-size-fits all blockbusters. ATMPs entail gene therapy, somatic cell therapy and tissue engineered products. This presentation explores in view of the applicable legislation about how ATMPs are regulated. The role of the committee for advanced therapies (CAT) will be explored in the marketing authorization process and what are the opportunities and pitfalls? In this presentation, the hurdles and issues to consider beforehand will be discussed i.e., How will ATMPs and precision medicine change the pharmaceutical market; what could be the legal implications; How about GMP; How about product liability; and What does the hospital exemption entail in the light of ATMPs. If the ATMP aims to treat patients with an unmet medical need, timely access opportunities may apply. Furthermore, precision medicine may need genetic data before treatment can be personalized - this concerns personal data. What issues should be considered in view of the general data protection regulation (GDPR)? In short, this presentation provides a snapshot of what should be considered in the light of ATMPs used in precision medicine. This presentation may yield a lively discussion afterwards.

Recent Publications

1. Nijland H M J, Ruslami R, Stalenhoef J E, Nelwan E J and Alisjahbana B (2006) Exposure to rifampicin is strongly reduced in patients with tuberculosis and type 2 diabetes. Clinical Infectious Disease 43(7):848–854.
2. Nijland H M J, L'homme R F A, Rongen G A P J M, Uden P Van and Crevel R Van (2008) High incidence of adverse events in healthy volunteers receiving rifampicin and adjusted doses of lopinavir/ritonavir. AIDS 22(8):931-935.

Biography

Hanneke Later-Nijland is an Attorney at law at Axon Lawyers, Amsterdam, Netherlands and moreover, she has been trained as a Pharmacist. Furthermore, she is holding a PhD in Clinical Pharmacokinetics and is a former Inspector for Clinical Trials and Pharmacovigilance at the Netherlands Inspectorate for Healthcare (IGZ). She specializes in European and national legal and regulatory issues relating to medicinal products. In her practice, she advises clients of life sciences, healthcare and litigates on a wide range of issues, often with a regulatory focus. Her areas of expertise in the medicinal products field covers marketing authorizations, reimbursement, compliance, pharmacovigilance and advertising issues. In addition, she also assists clients with product liability issues and IP and regulatory issues in transactions in the life sciences sector. Furthermore, she is a Lecturer at Leiden University Medical Centre. She regularly speaks and publishes on (new) European legislation and the impact of recent judgments in the sector.

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Henry M Sobell, J Biotechnol Biomater 2018, Volume 8
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Henry M Sobell

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The centers of premeltons signal the beginning and ends of genes

Premeltons are examples of emergent structures (i.e., structural solitons) that arise spontaneously in DNA due to the presence of nonlinear excitations in its structure. They are of two kinds: B-B (or A-A) premeltons form at specific DNA-regions to nucleate site-specific DNA melting. These are stationary and, being globally nontopological, undergo breather motions that allow drugs and dyes to intercalate into DNA. B-A (or A-B) premeltons, on the other hand, are mobile, and being globally topological, act as phase-boundaries transforming B- into A-DNA during the structural phase-transition. They are not expected to undergo breather-motions. A key feature of both types of premeltons is the presence of an intermediate structural-form in their central regions (proposed as being a transition-state intermediate in DNA-melting and in the B- to A-transition), which differs from either A- or B-DNA. called Beta-DNA, this is both metastable and hyperflexible and contains an alternating sugar-puckering pattern along the polymer-backbone combined with the partial-unstacking (in its lower energy-forms) of every other base pair. Beta-DNA is connected to either B- or to A-DNA on either side by boundaries possessing a gradation of nonlinear structural-change, these being called the kink and the anti-kink regions. The presence of premeltons in DNA leads to a unifying theory to understand much of DNA physical-chemistry and molecular-biology. In particular, premeltons are predicted to define the 5' and 3' ends of genes in naked-DNA and DNA in active chromatin, this having important implications for understanding physical aspects of the initiation, elongation and termination of RNA-synthesis during transcription. For these and other reasons, the model will be of broader interest to the general audience working in these areas. The model explains a wide variety of data, and carries within it a number of experimental predictions all readily testable as will be described in the presentation.

Recent Publications

1. Sobell H M (2016) Premeltons in DNA. Journal of Structural and Functional Genomics 17(1):17-31.
2. Sobell H M (2009) Premeltons in DNA. A Unifying Polymer Physics Concept to Understand DNA Physical Chemistry and Molecular-Biology. Explanatory Publications ISBN-978-0-615-33828-6.
3. Sobell H M (2013) Organization of DNA in Chromatin. Rather than bending uniformly along its length, nucleosomal DNA is proposed to consist of multiple segments of B- and A- DNA held together by kinks when forming its left-handed toroidal superhelical structure. Explanatory Publications ISBN-978-0-692-01974-0.

Biography

Henry M Sobell completed his studies at Brooklyn Technical High School (1948-1952), Columbia College (1952-1956) and the University of Virginia School of Medicine (1956-1960). Instead of practicing clinical medicine, he then went to the Massachusetts Institute of Technology (MIT) to join Professor Alexander Rich in the Department of Biology (1960-1965), where as a Helen Hay Whitney Postdoctoral Fellow, he learned the technique of single crystal X-ray analysis. He then joined the Chemistry Department at the University of Rochester, having been subsequently jointly appointed to both the Chemistry and Molecular Biophysics departments (the latter at the University of Rochester School of Medicine and Dentistry), becoming a full tenured Professor in both departments (1965-1993). He is now retired and living in the Adirondacks in New York, USA

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