# Senior Regulatory Advisor & Principal Consultant in Biologics Development


**Name:** **Dr. Hoss A. Dowlat**

**Nationality:** **German, British and Canadian**

**Education:** A' Levels: Heles Grammar School, Exeter, UK; **BSc**. 1st Class with Honours: London University, UK; **Ph.D.** East Anglia Norwich, UK; **Post Doc**: Royal Society European Fellowship, CNRS, Gif-Sur-Yvette, Paris, France, with Nobel Laureate Sir Derek Barton

**Title:** **Vice President, Global Strategy, Regulatory & Scientific Affairs,**

**Company:** **PharmaBio Consulting, Freiburg, Germany**

**EMA/SME/C/030/16/R10**

**Linkidin** : Under: Dr. Hoss A Dowlat


**Summary of Experience:**

**Specialties**:

**REGULATORY AFFAIRS.** EU-EMA/USA-FDA, LICENCING MAA/NDA/BLA (351a)/BLA (351k), BIOLOGICS, BIOSIMILARS, CELLULAR AND GENE THERAPIES, ORPHANS, SCIENTIFIC ADVICE OF MEDICINES. PHARMACEUTICAL, NON-CLINICAL AND CLINICAL DEVELOPMENT. CTAs/INDs. LEAD ADVISOR, REVIEWER AND WRITER OF ALL MODULES OF THE CTD-MAA/BLA/NDA, INCLUDING QOS, OVERVIEWS AND PRODUCT INFORMATION.

**CORPORATE DUE DILIGENCE.**

Dr. Hoss Dowlat leads an international team of drug development Principal Consultants at his self-owned PHARMABIO CONSULTING established in 2010. He also usually assumes a leading role in cross-organization pharmaceutical company early- and late-stage development and their service Providers: CM&C (laboratory – R&D and QC/QA testing; manufacturing - CDMOs), nonclinical (CROs) and clinical (CROs). His experience encompasses strategic regulatory and development support and Due Diligence to *circa* 140 client Pharma companies and international management consulting and pharmaceutical service companies from across all Europe, USA, Canada, Australasia, China, Korea, Taiwan, Japan, India, Russia, Ukraine, Switzerland and Israel and the financial sectors New York US and London UK. Such extensive and diverse activities provides PHARMABIO CONSULTING a unique industry-wide and Agency-wide network internationally.

Dr. Hoss was 2000-2010 Vice-President, Technical, Drug Development and Regulatory Global Strategy Services, at the leading CRO PAREXEL INTERNATIONAL providing direct multidisciplinary Quality-Nonclinical-Clinical consulting to support Phase 1, 2, 3 & 4 programs to meet EMA and FDA requirements pre- and post-approval. Prior to this he managed drug development programs and registrations in several international Pharma companies.

Dr. Hoss is German-British-Canadian, educated in England to B.Sc. and PhD level, and was also a recipient of a Post-doctoral European Royal Society Fellowship award, reporting to a Nobel Laureate in Paris. He has over 36 years of drug development experience in over 16 therapeutic areas in the EU and North American pharmaceutical industry, 30 years of which have been in regulatory affairs.

His strength includes **therapeutic proteins** such as **biosimilar monoclonal antibodies, infusion proteins, antibody-drug conjugates and human and analogue insulins; also, peptide complexes such as glatiramer, heparins, polypeptides and enzymes.** He has substantial **Orphan Drugs** development experience, additionally, and is applying it to niche area of **orphan biosimilars** as well as **Adeno-associated virus (AAV) vectors**. Experienced in Advanced Therapeutic Medicinal Product (**ATMP**) cellular and gene Products. Has unique insights into the **Quality, Nonclinical and Clinical FDA-EMA requirements** applied to these fields.

Extensive experience preparing clients for FDA meetings and has led, managed and attended FDA meetings

across CDER & CBER Divisions/Offices, in particular, formal Type B and Type C, NDA/BLA and BsUFA BLA (351k) Advice (Advisory and Types 1, 2, 3 & 4), Interact FDA meetings for ATMPs and presubmission FDA meetings.

Highly experienced with EU: EMA MAA presubmission meetings, MAA Rapporteur/Co-rapporteur presubmission meetings, D120 and D150 Clarification meetings, Oral Explanations, and SAWP/CHMP/EMA Scientific Advice.

Successful in Breakthrough Therapies development with the FDA, and PRIME products development with the EMA. Regulatory leadership of AAV vector, CAR T -Cell, and Dendritic Cell therapy meetings with OTAT/CBER/FDA, and 2021 MHRA ATMP meeting.

Pioneer in European biosimilar approvals, starting as regulatory lead to one of 2 EU Biosimilar MA somatropin (hGH) approvals in April 2006. Expanded expertise on biosimilars to USA and worldwide to present day.

Hoss has published many milestone articles, book chapters and lectures on biosimilars 2012-2019 including H. A. Dowlat*, M. K. Kuhlmann, H. Khatami & F. J. Ampudia-Blasco, *Interchangeability among reference insulin analogues and their biosimilars: regulatory framework, study design and clinical implications*, Diabetes, Obesity and Metabolism 2016 (John Wiley & Sons Ltd). doi:10.1111/dom.12676 3.

Hoss is a Referee for the high impact journals mAbs and DOM.

He is also a well-known international trainer (to Pharma and Regulatory Agencies in London, Basle and on- site) and conference and webinar presenter in EU/US regulatory affairs, biologics/biosimilars, orphans, combination drugs/biologics, Scientific Advice, the Common Technical Dossier (MAA/NDA/BLA), Labeling (prescriber and patient), clinical safety, pharmaceutical, non-clinical and clinical development.

- Hoss is a well-established pharmaceutical expert (CM&C of biologics and biosimilars drug substance, and all pharmaceutical forms of corresponding drug product), non-clinical expert (*in vitro* pharmacology, safety pharmacology, pharmacokinetics, pharmacodynamics, and acute toxicology; especially supporting comparability and similarity) and clinical expert (clinical pharmacology, bioequivalence, efficacy & safety, and pharmacovigilance; including Phase 1 and Phase 3 equivalence studies supporting biosimilarity), and overall transcontinental regulatory affairs strategist in medicines.

- Eight years in drug discovery in a research-based, multinational pharmaceutical company in the UK.
- Eight years in the pharmaceutical industry in North America, playing a significant role in the pharmaceutical and clinical development and registration of new drugs, generic drugs and biologicals.
- Six years of regulatory affairs consulting experience prior to PAREXEL, consisting of: two years as a consultant to American multinational and medium-sized pharmaceutical companies, while at a foremost CRO PHOENIX International (MDS) based in Montreal; two years as a consultant in an established UK medical and regulatory agency in London (QUANTUM-WELLS); and two years as an independent consultant to American and European companies in Hamburg, Germany.
- Ten years as Vice President and Principal Consultant in drug development and regulatory affairs as expert in pharmaceutical (extensive in comparability and similarity), nonclinical and clinical (focus on clinical safety) and labeling, leading international Teams, at PAREXEL CONSULTING. Recognized Opinion Leader and champion of PAREXEL Drug Development Consulting practice. Used resources across the CRO and collaborated with Pharma client multidisciplinary teams and their external experts and CROs for transcontinental programs. Successfully accomplished several multi-million dollar consulting projects of biologics, biosimilars and new chemical entities.
- Established a niche **regulatory consulting** company PHARMABIO CONSULTING in central Europe with world-wide clientele with particular emphasis on biologics and biosimilars. Supports **large and small Pharma**, also drug development/Pharma collaborations for past 16 years, which is ongoing. Also, has served as **advisor to the financial sector** in London and New York.

**Employment History:**

**Vice President consulting (2010-present), PHARMABIO CONSULTING**
Providing high level strategic consulting and leadership (with up to 6 PharmaBio team members per project) in own joint-founded company:

- **Regulatory affairs** and drug development Quality-Safety-Efficacy MAA/NDA-BLA support EU and USA. Registration of medicines. Advice to Pharmaceutical industry and financial investor institutions on special drug classes such as **biosimilars or orphans or Advanced Therapy Medicinal Products (ATMP's) or biospecific antibodies or antibody drug conjugates (ADC's) or proteins or enzymes or peptides, peptide complexes, polysacharide mixtures (LMWH) and small molecules** and overall risks of success or failure.
- Leading **EMA Scientific Advice**, **Protocol Assistance**, Orphan Drugs Designations, PRIME eligibility, Paediatric Investigational Plans (PIPs), **safety** Risk Management Plans (RMPs) and EU **Pharmacovigilance** Good Practices regulations.
- Leading **FDA** Type B&C, BsUFA BPD2&4, **INTERACT** (OTAT/CBER) meetings, Rare Pediatric Disease (**RPD**) Priority Review (designation and voucher), Breakthrough & Regenerative Medicine Advanced Therapy (**RMAT**), Fast-track etc.
- **Due diligence** support in-licensing or out-licensing. Facilitating partnership/joint agreements of Pharma.
- Offering **thought leadership** in biologic/biosimilar/drug development by a harmonized strategy for EU/US and internationally and a unique problem-solving consulting approach. Written major articles in peer review publications, presented webinars, conference lectures, provided conference chairmanship and trainings for regulatory, pharmaceutical, nonclinical and clinical executives.
- **Internationally recognized specialist in biosimilars development and registration EU and USA.**
- Regulatory expert in the development of cellular and genes (stem cells, chondrocytic cells, dendritic cells, autologous cells, CAR-T cells, and gene adeno-associated virus vectors (AAV's) products.
- **Orphan drug** (OD) development EU/US in parallel. OD and RPD designations.
- And ***all activities*** **below**.

**Vice President (Oct 2006 - 2010), Principal Consultant (Sept 2004-Oct 2006), Director Regulatory Affairs (Jul 2002-Sep 2004), Manager Regulatory Affairs (from Jul 2000-Jul 2002), PAREXEL International, PAREXEL CONSULTING, Office Freiburg, Germany, 2000-2010**

Providing high level strategic consulting and leadership (with up to 40 Parexel team members per project) in:

- Addressing and solving pharmaceutical, nonclinical and clinical challenges facing biosimilars and novel biologics impacting regulatory filings. Leading timely consultations with the EMA and FDA.
- Full international drug development programs, covering all chemistry, manufacturing and control (CMC), nonclinical and clinical aspects of small molecules, biologics and advanced therapies (cells, vaccines, genes), with proactive technical leadership or strategic project and business management.
- Drug safety, particularly the EU Risk Management Plan and Module 2.7.4.
- Paediatric Investigational Plan (PIP).
- Optimising labelling (EU: SmPCs, package patient information leaflets and package labels; US: package inserts), pre-, peri- and post-approval: with focus on conditions of use, safety mitigation, and readability issues.
- Due Diligence of new drug/biologics candidates or technology platforms, and scientific or regulatory packages of supporting data and information.

Furthermore, providing a full regulatory and drug development service to the pharmaceutical industry:

- Registering medicines, including Orphan's, in Europe (centralised procedure through EMA and national procedure) or North America (USA or Canada) by the most strategic and shortest route. Pioneering with a first (joint) EU approval of a somatropin hGH biosimilar in April 2006 and subsequently approval in USA. Led the second Pharma industry meeting with FDA on biosimilars in 2005. Later developed epoetin, filgrastim, recombinant monoclonal antibodies, fusion proteins, antibody drug conjugates, insulins etc leading to further approvals 2006-2026.
- Established PAREXEL as a leading worldwide service provider for biosimilars in Europe, USA, Korea, India, Taiwan and China. Designed, ratified with EMA/FDA, and executed Quality (comparable physicochemical, biochemical and stability *et cetra* against Originator), Nonclinical (comparable *in vitro*) and Clinical (PK/PD bioequivalence and Phase 3 safety & efficacy) testing studies to secure approval of biosimilars.
- Writing the Quality Overall Summary (Module 2.3), the Non-clinical Overview and Clinical Overview of the eCTD/MAA/NDA. Also, addressing other key CMC, QC/QA, GMP, GLP and GCP issues concerning dossiers of an extensive scope of products. These included NCE/NME, biologics, cellular products and vaccines.
- Advising on labelling and pivotal CMC, preclinical, or clinical issues, Modules 2.4 and 2.5 Overviews, and all CTD Modules 1-5, in order to support registration packages. Writing the Overviews as designated Expert.
- Accelerating the testing and marketing approval of new medicines, new biotech biologicals, biosimilars, generic drugs, or advanced therapies such as genes, cellular products and vaccines, or herbal (botanical) medicines and drug/drug or drug/biologic or biologic/biologic or drug/device combination products.
- Consulting on pharmaceutical development of monotherapy and combination products of small molecules and macromolecular biotech/biological substances: including sterile and injectable drugs, modified release orals, inhalers, and topicals regarding formulating, manufacturing, specifications and test methods, stability, impurity and degradation profiles.
- Advising on pharmaceutical equivalence, biocomparability and biosimilarity issues.
- Supporting clinical Phase 1 and Phase (biosimilars) or Phase 1/2/3 (novel products) studies through pivotal study design and timely filings. Also, ensuring that the safety reporting obligations to regulatory authorities are met and post-marketing pharmacovigilance is addressed adequately in PSURs and writing of the Summary of Product Characteristics (SmPCs) (EU)/Package Inserts (US).

Publishing on a wide scope of international regulatory affairs aspects of medicines, including as a co-author of a 290 page SCRIP report on pharmacovigilance.

Presenting at international conferences and training (onsite/offsite) Europe wide industry executives and regulatory authority/agency officials in the most up to date international regulatory requirements concerning Advanced Therapies, Biosimilars, Follow-on-Biologics, the CTD-MAA/NDA/BLA modules and dossier, (quality, non-clinical, safety and efficacy) or clinical CTD-IND/CTA-IMPD; Product Information/all aspects of international labeling; and aligning and harmonising SmPCs and PIs; EU enlargement, EU Variations or US Supplements; combination products; and Scientific Advice National/EMA/FDA.
Therapeutic areas include immunology, pain, oncology, endocrinology, hepatology, asthma, COPD, haematology, stroke, epilepsy and rare diseases.

**Senior Consultant, Regulatory Affairs, <u>QUANTUM MEDICAL COMMUNICATIONS LTD</u> (CRO), Kent, UK, 1998-2000**
Prepared and advised on MAA centralised and MAA packages, pharmaceutical and clinical expert reports, PSURs (particularly sections 6, 9 and 10), product information (SmPC, package leaflets and labels) and CTX's. Contributed strategic pharmaceutical, preclinical, clinical, and pharmacovigilance technical insights. Provided consultancy on a range of regulatory issues.
For one centrally approved oncology liposomal product, influenced the SmPC label claims, also wrote the pharmaceutical expert report, tabular formats and part II (18 volumes of CMC) of a complex four-component

liposomal injectable product. This MAA Submission received only minor pharmaceutical consolidated questions from the CPMP, leading to a positive Opinion and EU Commission Approval, even though, immediately prior to the start of the MAA preparation, the NDA was withdrawn in the USA after unfavourable conclusions of an FDA advisory committee.
Supported regulatory strategy for somatropin (Serono) in Dwarfism.
Therapeutic areas of cardiovascular, immunosuppression, narcotic addiction, asthma, HRT hormones, cancer, various dermatologicals, growth hormone, antiinfectives.

**Senior Consultant, Regulatory Affairs, PHARMABIO CONSULTING, Hamburg, Germany, 1996-1998**
Prepared Canadian registration dossiers, New Drug Submissions (NDSs), for a North American-European partnership starting with MAA packages. Co-ordinated pharmaceutical development. Prepared Canadian 'QIS-P' Comprehensive Summaries of CMC of parenteral products. Medical writing. Drug licensing. Therapeutic areas of anaesthetics, cardiovasculars, and antiinfectives.

**Manager, Regulatory Affairs, NOVOPHARM INC (Pharma), Toronto, Canada, 1992-1995**
As pharmaceutical and regulatory expert on parenteral drugs, registered Canadian sterile medicines for injection (conventional drugs, biologicals and biotechnology drugs), four of which were first entry, and co-ordinated North American and European Drug Development activities. Negotiated the approval of MAA to NDS switches originating from TEVA pharmaceuticals, through expansion of data (spearheading the pharmaceutical development) and rewrite. Set specifications, tests, and limits of drug substances and products, and related substances, negotiated their acceptance with authorities and followed through liaising with manufacturing plants to produce first marketing batches. Evaluated drug master files (DMFs), and negotiated all drug substance quality criteria by consulting with Italian, Swiss, German and Spanish suppliers to meet the strict requirements of the Canadian authority. Consulted on issues concerning: vial, rubber stopper and lyophilisation; pharmaceutical equivalence; compatibility and stability on reconstitution and further dilution with admixtures. Prepared the clinical parts of a NDS for Biotechnology Corporation's somatropin.
Therapeutic areas of oncology, cardiovascular, Alzheimer's, spinal cord injury, growth hormones and antibiotics.

**Manager, Corporate Affairs, SEARLE Canada (Pharmacia) (Pharma), Toronto, Canada, 1991-1992**
Filed Canadian NDSs and INDs and provincial submissions for oral dosage forms. Also, Medical Information Officer.
Therapeutic area: cardiovascular.

**Associate Director, Regulatory Affairs and New Drug Development, PHOENIX INTERNATIONAL LIFE SCIENCES (CRO), Montréal, Canada, 1989-1991**
Consulted for multinational and medium-sized pharmaceutical companies on regulatory and scientific aspects of dossiers. Co-ordinated the regulatory activities of Phoenix by interacting with 9 Divisions from 4 Bureaus of the Health Protection Branch (HPB, Canada) and 10 Divisions (8 offices) from 4 Centers of the FDA. Designed PD, PK/PD and bioequivalence studies. Supported the president in special projects. Advised on pharmaceutical development of medicinal products derived from hygroscopic and trace metal-sensitive drug substances.
Therapeutic areas of migraine, pain, antiinflammatory, antiemetic, diabetes, cardiovascular and asthma.

**Project Manager, Regulatory Affairs, PHARMASCIENCE INC (Pharma), Montréal, Canada, 1987-1989**
Developed New and Generic drugs to support registration. Interacted with 4 Divisions from two Bureaus of the Health Protection Branch (HPB) of Health Canada to clear INDs and NDSs. Pharmaceutical development, including formulation, manufacturing and testing issues of sterile opthalmic and inhalation solutions, and metered dose inhalers. Clinical design and development. Coordinated third party manufacturing. Pharmaceutical equivalence. Therapeutic areas of asthma, rhinitis, Alzheimer's and conjunctivitis drugs.

**Senior Scientist, Fisons RHONE-POULENC (Aventis) (Pharma), Loughborough, UK, 1979-1987**
Chemical synthesis, medicinal chemistry, drug discovery and preclinical research screening as a part of a project management team. Therapeutic areas of asthma, rhinitis, immunomodulation, arthritis, psoriasis, CNS and ulceration. A co-inventor of [$H^+$, $K^+$-Atpase] inhibitors.

**Education:**

- Awarded Post-doctoral European Royal Society Fellowship, 1978-1979
- Ph.D. Organic Chemistry, Norwich, UK, 1978
- BSc. Chemistry, London, UK, 1st Class with Honours, 1974.

**Language Skills:**

English mother tongue; French: fluent, German: fluent.

**Professional Associations:**

DIA, RAPS, TOPRA (EU), PDA.

**Publications (24) 1999-2011:**

Hoss Dowlat and Angela Gisby. Opportunities, challenges and pitfalls in reshaping full transatlantic regulatory dossiers, **switching NDA /NDS to MAA packages**, Journal of the European Society of Regulatory Affairs, ESRA Rapporteur, September/October 1999, Volume 6, Number 5, pages 19-23.

Hoss A. Dowlat and Angela S. Gisby. Key elements of the **European Submission**, Magazine of the Regulatory Affairs Professionals (RAPS) (USA), Regulatory Affairs FOCUS, May 2000, pages 11-16.

Hoss Dowlat and Angela Gisby. Seeing through the complex maze of **USA vs. European guidances**, Journal of the European Society of Regulatory Affairs, ESRA Rapporteur, November/December 1999, Volume 6, Number 6, pages 8-13 (lead article).

Hoss A. Dowlat and Angela S. Gisby. **Health economics** in decision-making in Europe; Journal of the British Institute of Regulatory Affairs (BIRA), The Regulatory Review, 1999, Volume 2, Issue 8, pages 14-17.

Hoss Dowlat. N.O.C., Magazine of the Canadian Association of Professional Regulatory Affairs (CAPRA), **European Update**: what's new in Europe, October 1998, pages 6 and 15.

Hoss Dowlat. N.O.C., (CAPRA), European update: **Mutual Recognition Procedures** or lack thereof, January 1999, page 6.

Hoss Dowlat. N.O.C., (CAPRA), European update: key elements of the **European submission**, April 1999, pages 11-12

Hoss Dowlat. N.O.C., (CAPRA), European update: **health economics** in decision-making in Europe, August 1999, pages 1, 10 and 11 (lead article).

Hoss Dowlat. N.O.C., (CAPRA), European update: **Centralised Submissions**, October 1999, pages 6-7.

Hoss Dowlat. N.O.C., (CAPRA), European update: **switching NDS/NDA to MAA** packages, January 2000; pages 1, 6, 7, 11 (lead article).

Hoss Dowlat. N.O.C., (CAPRA), European update: the Package Insert in Europe: **readability criteria of the Patient Information Leaflet**, September 2000.

Hoss Dowlat. N.O.C., (CAPRA), European update: **Scientific Advice** in the European Union (PART I), January 2001, pages 4 and 15,

Hoss Dowlat. N.O.C., (CAPRA), European update: Scientific advice in the European Union (PART II), April 2001, pages 17-18.

Hoss Dowlat. N.O.C., (CAPRA), European update: difficulties with **the lack of harmonised labelling**, October 2001, page 10.

Hoss Dowlat. N.O.C., (CAPRA), European update: organizational changes in the European union, July 2002, page 6.

Hoss Dowlat. N.O.C., (CAPRA), European update: advancements in the **EU Procedures** 2002-2005 and enlargement of the eu, April 2002, pages 1 and 26 (lead article).

Hoss A. Dowlat and Susan Sandler. Scrip Report; **Pharmacovigilance**: effective safety surveillance strategies; chapter 3 Pharmacovigilance—the European perspective; Strategic Management Report Series, PJB Publications Ltd, 11 April 2002, pages 97-147.

Hoss Dowlat. N.O.C., (CAPRA), New opportunities: the anticipated impact of the new **orphan drugs incentive in Europe** (PART I), October 2002, page 7.

Andy Morffew, Alberto Grignolo, Bruce Babbitt, Hoss A. Dowlat, Cecil Nick, Good Clinical Practice Journal, 2003, **Regulatory challenges facing start-up biotech** companies.

Hoss Dowlat, (REGULATORY FOCUS), Fresh insights into the practicalities of **developing biosimilar biologics**, October 2009.

Hoss Dowlat, N.O.C., (CAPRA), European and Canadian experience providing insights into **developing biosimilar or subsequent entry biologics**, Number 74, Spring 2010.

Hoss Dowlat, N.O.C., (CAPRA), Major impact of 2010 **post-approval EU Variation** regulation (ec) 1234/2008 on pharmaceutical companies, Number 75, Summer 2010.

Hoss Dowlat, Rapporteur (TOPRA), The current **status of biosimilar biologics** – an international perspective, part 1, p.24-27, 2010. Regulatory Rapporteur – Vol 7, No 9, September 2010, p.24-27.

Hoss Dowlat, Rapporteur (TOPRA), The current status of **biosimilar biologics** – part 2: practical considerations in international development through **European lessons learned**, 2010. Regulatory Rapporteur – Vol 7, No 10, October 2010, p.8-11.

Hoss Dowlat, Rapporteur (TOPRA), The importance and impact of the **EU RMP and US REMS** to risk–benefit assessments, Regulatory Rapporteur – Vol 8, No 2, February 2011, p.20-23.

**PharmaBio's publications (17) in drug/biologics/biosimilars development in the EU and USA 2012-2018:**

Hoss Dowlat, Regulatory focus, Fresh insights into the **practicalities of developing biosimilar biologics**, October 2009.

Hoss Dowlat, N.O.C., (CAPRA), **European and Canadian experience** providing insights into developing **biosimilar or subsequent entry biologics**, Number 74, Spring 2010.

Hoss Dowlat, Rapporteur (TOPRA), The **current status of biosimilar biologics** – **an international perspective**, Part 1, p.24-27, 2010. Regulatory Rapporteur – Vol 7, No 9, September 2010, p.24-27.

Hoss Dowlat, Rapporteur (TOPRA), The current status of **biosimilar biologics** – Part 2: Practical considerations in **international development through European lessons learned**, 2010. Regulatory Rapporteur – Vol 7, No 10, October 2010.

Hoss Dowlat, Rapporteur (TOPRA), The importance and impact of the **EU RMP and US REMS** to risk–benefit assessments, Regulatory Rapporteur – Vol 8, No 2, February 2011.

Hoss Dowlat & KL Rost, **Biosimilars Breaching Borders: How FDA & EMA Find Common Ground**, Regulatory Focus (USA), March 2012.

Hoss Dowlat, Perceptions and reality of **clinical safety of biosimilars**, present and future: **EU perspectives and US prospects**, 2012 Part 1, Regulatory Rapporteur – Vol 9, No 4, April 2012.

Hoss Dowlat, Perceptions and reality of **clinical safety of biosimilars**, present and future: EU perspectives and US prospects, 2012 Part 2, Regulatory Rapporteur – Vol 9, No 5, May 2012.

Hoss Dowlat, **How Safe Are Biosimilars?** Implications of FDA and EMA Guidances and **European Experience** since 2006, Regulatory Focus (USA), Part 1. Regulatory Focus (USA), May 2012.

Hoss Dowlat, How Safe Are Biosimilars? Implications of FDA and EMA Guidances and European Experience since 2006, Regulatory Focus (USA), Part 2. July 2012.

Hoss Dowlat, **RAPS Book**, **Fundamentals of International Regulatory Affairs**, Second Edition, Chapter Advancement of Biosimilars Development in Europe, USA, and Internationally, 2013, published October.

Hoss Dowlat, **Prefilled Syringes and Related Biologic Drug/Devices**, Pharmaceutical Outsourcing, Volume 14, Issue 7, November/December 2013.

Hoss Dowlat, Opportunity of a **new class of biosimilar orphan biologic medicines** offering access to affordable medicine, Paper for the 5th Orphan Drug Summit, Copenhagen 17/18 September 2015, April 2015.

Hoss A Dowlat (lead author), Martin K. Kuhlmann, Hootan Khatami, Francisco Javier Ampudia-Blasco, "**Interchangeability among reference insulins and their biosimilars**: regulatory framework, study design, and clinical implications", Diabetes, Obesity and Metabolism DOM, April 2016. http://onlinelibrary.wiley.com/doi/10.1111/dom.12676/abstract.

Hoss A Dowlat, The opportunities and challenges of **biosimilar** orphans (editorial), Expert Opinion on Orphan Drugs (Informa publishers), 7 April 2016. http://dx.doi.org/10.1517/21678707.2016.1171142.

Ulrike Hövelmann, Leszek Nosek, Hoss A. Dowlat, Amee Mehta and Tim Heise, Solumarv, **a regular human insulin**, and Isomarv, a **NPH-insulin** preparation, show **bioequivalence** to EU-marketed insulins, 76th Scientific Sessions, American Diabetes Association (ADA), New Orleans, USA, June 10-14, 2016.

Hoss Dowlat, Carsten Brockmeyer, Fiona Greer, Rick Lozano, Editorial by Stephanie Sutton, I'm a (Biosimilars) Believer!, **Four biosimilar gurus discuss successes and tackle the issues head on**, Medicine Maker, May 2018, Issue #0518.

**Conference lectures and public and in-house trainings (50) given 2001-2012:**

Hoss A Dowlat (Trainer). Mastering EU requirements for **pharmaceutical product labelling/package leaflets,** International Pharmaceutical Training (IIR Ltd; Informa Life Sciences), professional 2 or 3 day course for Industry and Competent Authorities, 3-4 July, 2001, Basle, Switzerland; December 6-7, 2001, London, UK; London, March

7-8, 2002, Basle July 1-2, 2002, London September 18-21, 2002, Munich December 2-4, 2002, and quarterly London 2003- 2013.

Hoss A Dowlat (Trainer). **Scientific advice**: Strategies to obtain maximum benefit from Scientific Advice, Informa Solutions (PTI), professional 2 day course for EU/US Pharma Industry, 2006, and January 2007, 2008, 2009, 2010, 2011, 2012.

Hoss A Dowlat (Trainer). **Introduction to Regulatory Affairs for Drug/drug and Drug/device Combination Products**, Informa Solutions (PTI), professional 2 day course for EU/US Pharma Industry, 2008, 2009, 2010, 2011.

Hoss A Dowlat (Trainer). **EU registration**, Informa Solutions (PTI), professional 3 day course December 2009, May 2011.

Hoss A Dowlat (Leader of Panel of Speakers 2nd day; also, Speaker 1st day), Understanding the **process of scientific advice** to avoid a negative CPMP opinion and ensure the successful registration of your product, (IIR Ltd), 23-24 October, 2000, London, UK.

Hoss A Dowlat (Speaker) Practical experiences of **harmonised SmPCs; PILs, and labelling in the EU** and its relevance for CADREAC, (IIR Ltd), 18 September, 2001, Budapest, Hungary.

Hoss A Dowlat (Speaker) **Tackling variations in the EU and USA** in a co-ordinated approach: is this achievable? Variations 2002 (IIR Ltd), 26-27 February, 2002, London, UK.

Hoss A Dowlat (Speaker) **Highlighting the pre- and post-EU enlargement challenges** and concerns to be faced by European industry (IIR Ltd), 22-23 April, 2002, Vienna, Austria.

Hoss A Dowlat (Speaker) **FDA and EMA/CPMP transcontinental regulatory precedents** - their impact on your development activities, BioM Munich, Biotech Development, 16 October 2002, Munich, Germany.

Hoss A Dowlat (Speaker and Panel) **Streamlining EU and US regulatory procedures** (focus biologics), Revisions of the Variations Regulation (IIR Ltd), 28-29 October, 2002, London, UK.

Hoss A Dowlat (Speaker and Panel) The far-reaching impact of the modern **EU wide patient leaflet, PILs, Packaging and Labelling** (IIR Ltd), 25-26 November, 2002, London, UK

Hoss A Dowlat and Kim Wharton (Course leaders), **Filing variations**, (IIR Ltd), professional 2 day course for Industry and Competent Authorities, 2002, 2003, 2004, London.

Hoss A Dowlat (Speaker and Chair) Far reaching implications of **viral contamination and strategies for their removal**, Registration of Biotechnology Products (IIR Ltd), 23-25 April, 2003, Copenhagen, Denmark.

Hoss A Dowlat (Speaker and Panel), Handling **the differences between EU and US regulatory procedures**, Revisions of the Variations Regulation (IIR Ltd), 14-15 May, 2003, London.

Hoss A Dowlat (Speaker and Session Organiser), The far-reaching present and future impact of **the new design European patient package information leaflet in communicating safe use of medicines**, Regulatory communication with patients and its implications for risk management: how are we doing and where are we going?, DIA US Annual Meeting (15-19 June), 18 June, 2003, Texas, USA.

Hoss A Dowlat (Speaker), Rationalising **EU and US post-approval procedures**, Variations and Life Cycle Management, 26 May, 2004, London, UK.

Hoss A Dowlat (Speaker), European insights into **the impact of the CTD**, Common Technical Document, Washington, 8 June, 2004.

Hoss A Dowlat (Speaker), Challenges in developing 'generic' biopharmaceuticals **similar biologics**, (Management Forum), Injectable products: Formulation Challenges, Solutions and TechnologyTrends, 24-25 October, 2005, London, UK.

Hoss A Dowlat (Course leader), Successfully managing the **filing of Variations**, (IIR Ltd), 21 November, 2005, London, UK.

Hoss A Dowlat (Chairperson), Examining the influence of **the 2003 change to classifications of Variations**, (IIR Ltd), 22-24 November, 2005, London, UK.

Hoss A Dowlat (Speaker), Preparing for submission through **the Decentralised Procedure**, (IIR Ltd), New Medicines Legislation, 25-26 January, 2006, London, UK.

Hoss A Dowlat (Speaker), Strategies for complying with **EU Directives in labelling and packaging**, (IIR Ltd), New Medicines Legislation, 25-26 January, 2006, London, UK.

Hoss A Dowlat (Course leader), Strategies to obtain **maximum benefit from scientific advice**, (IIR Ltd), 4-5 May, 2006, London, UK.

Hoss A Dowlat (Speaker), Moving your organisation towards **effective eCTD submission of Variations**, (Informa Life Sciences), 29-30 December, 2006, London, UK.

Hoss A Dowlat (Speaker), Examining the **revision of the Commission regulations** and its **impact on Variations** in terms of Marketing Authorisations, (Informa Life Sciences), 29-30 December, 2006, London, UK.

Hoss A Dowlat (Speaker), The impact of regulatory considerations on **biomanufacturing outsourcing** in Korea, BioKorea 2007, Seoul, Track 8, Topic 2.

Hoss A Dowlat (Speaker International Webseminar), Examining the most current **European regulatory advances** concerning the pharmaceutical industry, (Informa Life Sciences), 25 June, 2008, London, UK.

Hoss A Dowlat (Speaker), Taking **strategic advantage of a core eCTD dossier (MAA, NDA** etc): reduce time to submission and approval internationally, Lifecycle Management of the eCTD, (Informa Life Sciences), 28-29 October 2008, Amsterdam, The Netherlands.

Hoss A Dowlat (Speaker), Examining the practical impact of **the new guidelines on filing variations** for both industry and regulatory authorities, What are the opportunities, potential shortcomings and risks of the guidelines? How are regulatory authorities preparing for the practical impact of the guideline? Registration of Generics Summit, (Informa Life Sciences), 11-12 November 2008, Prague, Czechoslovakia.

Hoss A Dowlat (Speaker), Seminar zum management von wissenschaftlichen und ökonomischen herausforderungen in der frühen, **Klinischen entwicklung**, Streamlining Biotech Development Using International Regulatory Strategy, 3 April 2009, Max-Planck Biotech Centre, Martinsried, Munich, Germany.

Hoss A Dowlat (Speaker), ‚Conference Taizhou Medical City. **Drug and biologics development** in the EU and USA. critical **clinical and comparability** issues in new and biosimilar biologics. 2008, Taizhou, China.

Hoss A Dowlat (Speaker), **Streamlining biotech development** for the USA from IND to NDA/BLA using international regulatory strategy and increasing chances of approval, global bio tech forum, Seoul, June 2009.

Hoss A Dowlat (Speaker). The challenges and successes of **developing biosimilar medicines: European EU lessons learned**, global bio tech forum, June 2009. Seoul.

Hoss A Dowlat (Speaker). PAREXEL **streamlining biotech development** using international regulatory strategy, Seminar zum Management von wissenschaftlichen und ökonomischen herausforderungen in der frühen Klinischen entwicklung, July 2009, Berlin, Germany.

Hoss A Dowlat (Speaker). Informa Ltd, **Registration** of pharmaceuticals in the EU, Prague (November), Dubai (December), 2009.

Hoss A Dowlat (Speaker), PTI variations conference, Breakout Session, Planning, documentation and **lifecycle management for variations**, 2 December 2009, London, England.

Hoss A Dowlat (Trainer). **New 2010 variations**. March 2010 (2 day), London.

Hoss A Dowlat. Spring School, London, chair and speaker, Understanding **the role of the national regulators and the European Medicines Agency**; **Scientific advice** in European regulatory affairs; international conference on **harmonization** of technical requirements for registration of pharmaceuticals for human use (ICH), European Regulatory Affairs Spring School, 22-24 March, 2010, London, England.

Hoss A Dowlat (Speaker), Pharmaceutical development strategies for **life cycle planning, managing** the end of patent for medicinal products, DIA EU Annual Meeting, March 2010, Monaco.

Hoss A Dowlat (Speaker), DIA, **Scientific basis for clinical and regulatory requirements of drug fixed combination products**, combination products: developing an integrated regulatory plan that works, DIA US Annual Meeting (14-17 June), 18 June, 2010, Washington, USA.

Hoss A Dowlat (Speaker), DIA, Key considerations for **global strategies for biologics**, gaining **critical efficiencies** in global biotechnology drug development strategy, DIA US Annual Meeting (14-17 June), 2010, Washington, USA.

Hoss A Dowlat (Speaker), Topic: Regulatory standards for the approval of **biosimilar and interchangeables** regarding current 'biosimilar guidelines' 28 June, Global Bio & Medical Forum 2010, 28-29 June 2010, Seoul, Korea.

Hoss Dowlat (Speaker), EUCRAF Postgraduate Master Programme of Biotech-related Regulatory Affairs, **ICH process**: collaboration of the three regions **EU, US and Japan**, collaboration of EU agencies with FDA, collaboration of EU agencies with other agencies: **China, India, Brazil**, 17 September 2010, Freiburg, Germany.

Hoss Dowlat (Speaker), BioPractice, European experience of regulatory submissions development and registration of biosimilars medicines 2002-2010, **Essential biosimilars perspectives** for Indian pharma companies, Webcast, 29 Nov., 2010, Freiburg.

Hoss Dowlat (Speaker), BioPractice, **Essential regulatory perspectives** and best clinical and nonclinical practices for Indian pharma companies in support of EU and US MAA/NDA/BLA regulatory submissions, Webcast, 7 February, 2011, Freiburg.

Hoss Dowlat (Speaker), BioPractice, European experience of regulatory submissions development and **registration of biosimilars medicines 2002-2010,** essential biosimilars perspectives for American pharma companies, Webcast, 18 April, 2011, Freiburg.

Hoss Dowlat (Speaker), Informa Life Sciences, Introduction and international perspective: **regulatory intelligence**, Regulatory Information Management, 8/9 March 2011, Frankfurt.

Hoss Dowlat (Speaker), Informa Life Sciences, **Stability testing for drug or biologic/medical device combination** products, Stability Testing**,** 6/7 April 2011, Berlin.

Hoss Dowlat, (Speaker), Essential perspectives of biosimilar medicines, particularly the **major impact of pharmaceutical comparability**; 1st Protagen Well-characterized Biological Product Day, 11 April, 2011, Dortmund.

**PharmaBio Conference lectures, seminars and trainings (31) 2012-2019:**

Dr. Hoss A Dowlat, **Strategic insights into European (CHMP/EMA) and American (FDA) regulatory aspects of stability**, Establishing Accurate and Efficient Stability Design Stability Testing & Higher Order Structure of **Biologics**, Informa Life Sciences, 26th -27th September 2012, Berlin.

Dr. Hoss A Dowlat, **Leveraging Emerging Markets Approvals into a global regulatory strategy extending to the EU, USA and Japan: SME case study**, Global Regulatory Strategy, Informa Life Sciences, 27-28 November 2012 , Danubis Hotel | London.

Dr. Hoss A Dowlat, **Comparing and contrasting Regulatory Pathways (WHO, FDA, EMA),** 2nd Middle East conference on Biosimilars, Jordanian Association of Pharmaceutical Manufacturers (JAPM), 2012, 13/14 November, Amman- Jordan.

Dr. Hoss A Dowlat, **Risk assessment: approaches to ensure dose accuracy** within a EU/US regulatory compliance framework, Pre-Filled Syringes & Injector Devices for Biologicals, Informa Life Sciences, 5-6 December 2012 , Radisson Blu Hotel Berlin.

Dr. Hoss A Dowlat, Evaluating the **pathway for registration of Biosimilars in USA** to gain swift product approvals, Global Pharma Regulatory Summit, Mumbai, India, 12 March 2013.

Dr. Hoss A Dowlat, **Highlights of 2013 registration status of biosimilars in the EU**, Global Pharma Regulatory Summit, Mumbai, India, 13 March 2013.

Dr. Hoss A Dowlat, **Risk management of biosimilar products**: Challenges compared to development of originator biologics or small molecules, PTI Informa, In-house Pharma Training Course Istanbul, 25-26 March 2013.

Dr. Hoss A Dowlat, Expectation and opportunities of **Bringing Biosimilars from China to EU**, from Regulatory Point of View, 14 May 2013, 5th DIA China Annual Meeting (May 12-15), Beijing, China, May 13, 2013.

Dr. Hoss A Dowlat, **Cell Therapy and Biosimilar Development**, Opportunities, and Regulatory Considerations, 5th DIA China Annual Meeting (May 12-15), Beijing, China, , May 13, 2013.

Dr. Hoss A Dowlat, Exploring latest **FDA/EMA concepts of US-EU comparability** criteria based on biosimilars experiences, and potential impact on the life cycle of new biologics, International Broadcast, FDANEWS, 9 May 2013.

Dr. Hoss A Dowlat, Comparing and contrasting **strategic regulatory/clinical** perceptions and approval/use aspects of Inhalation Drug Combination Products internationally, 'Practically Assessing Emerging Economics for Inhalation Drug Products and Reviewing the Degree of Harmonisation', Informa, Berlin, 16 September 2013.

Dr. Hoss A Dowlat, When is an ADE, Not an ADR? How the EU's **Redefinition of ADR's Highlighting Medication Errors Impacts Global Labeling**, EU SmPC/US PI, and Pharmacovigilance Strategies.
The new EMA and FDA emphasis on medication errors, International Broadcast, FDANEWS, 28 August 2013.

Dr. Hoss A Dowlat, What is the latest **progress of O/D development and regulatory approvals in EMA/FDA/Japan PMDA and ROW**? Advances in the evaluation and development of orphan drugs, Executive Circles of O/D Summit, Midfield Media, Copenhagen, 11-13 September 2013.

Dr. Hoss A Dowlat, Understanding the **US regulatory system and relating to the EU regulatory framework** to facilitate best practices, PTI-Informa, Basle, 24-25 September 2013.

Dr. Hoss A Dowlat, When is an ADE, not an ADR? How the **EU's Redefinition of ADR's Highlighting Medication Errors Impacts Global Labeling**, EU SmPC/US PI, and Pharmacovigilance Strategies?, Pharmaceutical Labelling Summit, Informa Life Sciences, 9 – 10 October 2013.

Dr. Hoss A Dowlat, Highlights of 2013 approval and **clinical development status of biosimilars in the EU**: international impact, Late breaking Clinical Trial News 2013, ACRP 16th European Conference, Royal Academy of Medicine, Brussels, 14 November 2013.

Dr. Hoss A Dowlat (*training*, 6-day for Saudi FDA), Introduction to **Drug Development and Regulatory Affairs** in Major Regions, PTI-Informa, Riyyad and Jedda, Saudi Arabia, December 2013.

Dr. Hoss A Dowlat, Unique executive oversights into **biologics and biosimilars** including comparability criteria **EMA vs FDA**, approval strategy and market penetration, 6th International Seminar (1 Day), Princeton (Medical Faculty), NJ, USA, 4th August 2014.

Dr. Hoss A Dowlat, The **legal and regulatory FDA/EMA labelling framework** that drives biosimilar development in the US and EU, Regulatory Considerations and Market Access Strategies for Biosimilars, Informa Life Sciences' 11th Biosimilars conference, 22 May 2014, Berlin.

Dr. Hoss A Dowlat, Understanding and Reviewing the **Common Technical Document Format Dossiers**, Venue BRAC CDM, Savar Bangladesh, 3 Day *Training*, Directorate General of Drug Administration, Management Sciences for Health (MSH)/SIAPS Program, 23rd to 25th August, 2014.

Dr. Hoss A Dowlat, **EMA and FDA Approval Requirements** in EU and US, 1st Annual European Biosimilars Conference, Bernstein Research, London, 22 April, 2015.

Dr. Hoss A Dowlat, Executive Update of the **US FDA/EU EMA** of the New **Biosimilars** Product Class with Insights into Landmarks, **Approval Requirements**, Market Penetration and Opportunities, Princeton (Medical Center), NJ (USA), 1 Day *Seminar*, 14th August, 2015.

Dr. Hoss A Dowlat, Opportunity of a New Class of **Biosimilar Orphan** Biologic Medicines Offering Access to Affordable Medicines, Orphan Drugs Summit, Copenhagen, Denmark, 17-18 September, 2015.

Dr. Hoss A Dowlat, European Medicines Agency (EMA) and US FDA view of regulatory aspects of **pharmaceutical development of biological medicines resulting in high impact on efficacy and safety**, 19th Beijing International Healthcare Industry Forum Biological macromolecules symposium, 22nd Oct, 2015.

Dr. Hoss A Dowlat, Executive Perspectives of the **US/EU, FDA/EMA and international status of the New Biosimilar Product Class**: Insights, Landmark Approval Requirements and Opportunities, First Primetrics International Biosimilars *Seminar (*1 Day), Mumbai, India, 5th November, 2015.

Dr. Hoss A Dowlat, **Executive Perspectives of the New Biosimilar Product Class**: Insights, Landmark Approvals and Opportunities, Biosimilars Workshop, General Aspects/ Regulatory/ Clinical/ Formulation/ Monoclonals/ Insulins, Basle, 23rd November, 2015.

Dr. Hoss A Dowlat, Key considerations of **clinical development of biosimilars**, Theme 8: Clinical Trial Design of Biosimilar - Part 2 (May 17th), The 8th DIA China Annual Meeting, Beijing, May 15-18, 2016.

Dr. Hoss A Dowlat, Bio-Forum 2016, Alert to EMA EU and FDA US **regulatory aspects of biologics pharmaceutical development with consequences to efficacy and safety**, 18th Shanghai International Forum on Biotechnology & Pharmaceutical Industry, June 20-22, 2016.

Dr. Hoss A Dowlat, Executive Perspectives of the **New Biosimilar Product Class, Insights, Milestones, Regulatory Framework**, Lessons Approvals & Opportunities, Bioforum Ltd, Jerusalem and Kfar Hamacabiya, Israel, 14-15/18-19 March, 2018.

Dr. Hoss A Dowlat, CPhI-DIA Forum, Seminar, Executive Perspectives of the **New Biosimilars Product Class EU, USA and Internationally**, Shanghai, China, 20 June, 2018.

Dr. Hoss A Dowlat, Seminar, **Advances in the Biosimilar Class of Medicines**
Executive Perspectives on Development and Regulatory EMA FDA and CNDA (China) Aspects, DIA China Annual Meeting, Beijing (May 20-23), May 21, 2019.

**Webinar presentations (fee paid by attendees) (25) post-2012:**

Dr. Hoss A Dowlat with D. Christopher Ohly (Schiff Hardin LLP, Washington, D.C. USA), Interpretation & insights into the **FDA draft biosimilar guidances Scientific Considerations, Quality Considerations** & Q&A (Regulatory), & provision of an international perspective & context, 2 March 2012.

Dr. Hoss A Dowlat, **Comparing and contrasting FDA biosimilars guidances with EMA EU experience**, 27 April 2012.

Dr. Hoss A Dowlat, **FDA and EMA successful development and approvals strategy** for a biologic, 22 June and 6 July 2012.

Dr. Hoss A Dowlat, EU guidelines on **biosimilars of monoclonocal antibodies** (mAbs) & impact on comparability of mAbs EMA v FDA, 25 July 2012 (to USA and EU).

Dr. Hoss A Dowlat with M Blüggel (Protagen Protein Service GmbH, Dortmund, Germany), A EU/US Regulatory and Technical Practical Perspective on a **Comparability Campaign of Quality and Biological (In vitro) Testing Studies in Support of Biosimilarity**, 30August 2012.

Dr. Hoss A Dowlat, EU guidelines on **biosimilars of monoclonocal antibodies (mAbs) & impact on comparability** of mAbs EMA versus FDA, An overview of the newly released final 2012 EU guidelines on biosimilars of monoclonal antibodies (mAbs) and Indian overarching 2012 guideline, and impact on biosimilars EU-USA-India, 7 September 2012 (to India).

Dr. Hoss A Dowlat, Part 1, EU guidelines on **biosimilars of monoclonocal antibodies (mAbs) & impact on comparability of mAbs EMA v FDA** EU guidelines on biosimilars of monoclonocal antibodies (mAbs) & impact on comparability of mAbs EMA v FDA; Part 2, The Indian DP/CDSCO Overarching Biosimilars Guideline, 2012.

Dr. Hoss A Dowlat, FDA Approvals and Insights: Understanding **US-FDA Drug Regulatory Framework & Comparing & Contrasting with the Complex EU System**, 1 March 2013. (To USA.)

Dr. Hoss A Dowlat, Risks of not achieving comparability of biologics, **strategies of mitigating such risk, and state of the art practices in Quality-Safety-Efficacy in proving comparability**, 18 April, 2013. (To USA.)

Dr. Hoss A Dowlat, Exemplifying the **new EMA and FDA emphasis on medication errors** including the 2012 EMA redefinition of ADRs, Highlighting possible mitigation strategies internationally, BioPractice, July 18th, 2013.

Dr. Hoss A Dowlat, **Ethics Scandal of Big Pharma in China**, Personal Insights, 6 September 2013 (To EU/USA clients of Global consulting firm Gerson Lehrman Group).

Dr. Hoss A Dowlat, Highlights of 2013 **registration status of biosimilars in the EU**, 15 November 2013. (To EU/USA.)

Dr. Hoss A Dowlat, A Landmark for Biosimilars – Part II, **Update on biosimilar insulins and mAb**s, 21 November, 2013, (To EU/USA clients of Global consulting firm Coleman Research Group).

Dr. Hoss A Dowlat, The different **legal and regulatory labelling framework that drives biologics and biosimilar development in the EU and USA**, December 13th 2013.

Dr. Hoss A Dowlat, **Breakthrough 2013 approvals of biosimilars in EU,and current status, and possible impact in USA-Internationally**, 5 February 2014.

Dr. Hoss A Dowlat, Current **drug development pharmaceutical and clinical efficacy/safety/effectiveness** issues facing MAA applicants, 26 February, 2014.

Dr. Hoss A Dowlat, Executive insights into the **FDA "Purple Book"** Classification and other FDA initiatives regarding biologics and biosimilars, to USA, 26 September 2014.

Dr. Hoss A Dowlat, Unique executive perspectives into **biologics and biosimilars; EMA vs FDA**, approval strategy and market penetration, Biopractice, to EU/USA, 21 October 2014.

Dr. Hoss A Dowlat, The clinical, regulatory and business challenges and rewards of **Orphan development and approval EU and international**, Biopractice, to EU/USA, Jan 23, 2015.

Dr. Hoss A Dowlat, Executive insights into the **FDA "Purple Book"** Classification and other FDA initiatives regarding biologics and biosimilars, Biopractice, to USA, 20 February 2015.

Dr. Hoss A Dowlat, Executive Update of the **Biosimilars Product Class** followed by Questions and Answers, International Consulting Company GLG, **Broadcast to US/EU Financial Sector**, 25 February, 2015.

Dr. Hoss A Dowlat, Executive Update of the **US/EU status and opportunities of the new Biosimilars** Product Class, Biopractice, broadcast to USA industry, 27 May 2015.

Dr. Hoss A Dowlat, Executive insights into the FDA "Purple Book" Classification and other **FDA initiatives regarding biologics and biosimilars**, Biopractice, broadcast to USA industry, July 10 2015.

Dr. Hoss A Dowlat, Executive Overview of Current Biosimilars Advances, **Functional Comparability Studies for Biosimilar Development**, Biopharm, international live webcast, June 21, 2016.

Dr. Hoss A Dowlat, **Key considerations in development of biosimilars**, Advances in the approvals of biosimilars by the FDA since only in 4thQ2015, and a decade 2006-2017 of approvals by the EMA, Biopractice broadcast, May 2017.