Speid & Associates, Inc

SPEEDING NEW DRUGS TO MARKET®

Speeding New Biosimilars to Market™

BIOSIMILARS

Biosimilars are an important growth area for the pharmaceutical and biotechnology industries. Many large and small pharma companies are seeking to bring biosimilar products to the global market.

International Registration of Biosimilar Products

The release of the US biosimilar guidelines provides opportunities for companies to expedite these developments. Europe has a stringent and credible system of approval for biosimilars and has been approving biosimilars since 2006. Although biosimilars have been marketed in other countries like Mexico, China and India, these products would not meet the requirements of the US, Europe or other ICH regions without additional studies and work.

STRATEGY

EXPERTISE

Speid & Associates is well placed to advise companies in ICH and non-ICH countries, and to bring products to the global marketplace by building effective regulatory strategies. Success in the biosimilar arena will require a unique set of skills. Dr. Speid has a unique background which enables her to provide expert and strategic input to clients working in the area of biosimilars. The goal is always to expedite access of potential biosimilar products to the global marketplace.

Services

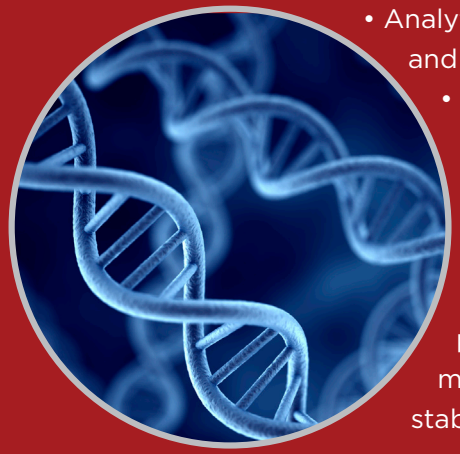
- Global strategic regulatory affairs services
- Conversion of development programs for biosimilar products marketed in non ICH markets for ICH markets
- Development of global clinical programs for biosimilar products
- Development of strategies for meetings with the major regulatory authorities
- Special services are available to the companies based in non-ICH countries as well as ICH countries

ONE-STOP-SHOP

Biosimilars are very complex products. The development of these products will require the collaboration of many experts with different expertises and skillsets. Very few organizations will have the range of expertises necessary in-house to assure the successful development of these products. To overcome this challenge, Speid & Associates has set up a One-Stop-Shop of services that are required to bring biosimilar products to the global marketplace. The expert services will be provided by Speid & Associates partner organizations. These organizations are carefully selected and qualified because of their track record and expertise.

The Speid & Associates partner organizations provide the following types of services:

- Global and international regulatory affairs
- Bioprocessing, including cell line development, optimization and characterization
- Analytical method development and validation
- Bioanalytical method development and validation
- Biological drug substance scale up, manufacture, release and stability testing
- Biological finished product fill finish scale up, manufacture, release and stability testing
- Patent litigation strategy
- Patent evaluation
- Monoclonal antibody Research and Development
- Offshore Research and Development centers (China, India)
- Toxicology houses
- Clinical research organizations
- Marketing and commercialization
- Reimbursement strategies
- Labeling development services
- Tools, products and related services
- Reference product procurement
- Consultancy services



EXPERTISE

Dr. Lorna Speid

Lorna Speid, B.Pharm.(Hons). M.R.Pharm.S., Ph.D., RAC is President of Speid & Associates, Inc. a regulatory and drug development consultancy based in San Diego, California. She works with small and large pharmaceutical companies, assisting them at the various stages of the drug development process, including US, European, international and global strategic regulatory affairs. Dr. Speid has an excellent track record of success in regulatory affairs, and is considered an expert in her field. She has registered therapeutics internationally, and has experience with all the major regulatory authorities. Her unique experience including developing NCEs, small molecules, biologicals, diagnostics, generics, combination products, and devices, enables her to be uniquely equipped to develop global regulatory strategies for biosimilars, and to register them.

Dr. Speid began her career as a pharmacist in the UK, after which she completed a Ph.D. at the Centre for Medicines Research International, into the Safety Assessment of Medicines, Pre and Post Marketing. She has worked for large as well as small pharma companies, including Sanofi Winthrop in the UK (now Sanofi-Aventis), Ciba Geigy and Novartis in Switzerland (at Headquarters). Small companies that she has worked for include Valentis, Inc. (Director of Regulatory Affairs), NewBiotics (Vice President Regulatory Affairs and Project Management), and Avera, Inc. (Vice President of Regulatory Affairs). Dr. Speid was an officer at the last two companies. She has a Bachelor of Pharmacy degree from the University of London, UK (Kings College), and a Ph.D. from the University of Wales, College Cardiff, UK.

Dr. Speid is the author of *Clinical Trials: What Patients and Healthy Volunteers Need to Know*, published by Oxford University Press. It is being marketed globally.

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Speid & Associates is a privately held regulatory affairs and drug development consultancy based in San Diego, California.

Speid & Associates assists life science companies move new chemical and biological entities to the finish line expeditiously by developing effective global regulatory strategies. The Company works at all phases of drug development and has experience working with all major regulatory authorities. Speid & Associates also conducts due diligence for investors and companies.

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