

## Global biotechnology product registration U.S & European Union

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Biotechnology research continually opens opportunities for the development of new biopharmaceuticals for human use. Consequently, integration of public healthcare and human welfare with the business of biotechnology is becoming a central challenge. However, the companies developing such products are often small and they may have insufficient knowledge of the possible regulatory aspects concerning such new products. Like major pharmaceutical firms, today's biotechnology companies must leverage their development programs internationally and penetrate global markets to remain competitive.

To maximize market penetration, most biologics developers are targeting the largest international markets for new medicines -the U.S. & European Union. Within these two "prize" markets, fundamental regulatory changes affecting biotechnology product regulation have been implemented recently.

The United States and the European Union share a common desire to provide a safe food supply and credible regulatory systems. However, they have adopted two very different regulatory approaches to deal with the increasing numbers of GM (genetically modified) food and feed products coming to market.

European Medicines Evaluation Agency (EMA) was installed as the regulatory gatekeeper for the European market. EU established that the EMA's new centralized procedure would be mandatory for virtually all significant biopharmaceutical products.

The U.S. module of Global Biotechnology Product Registration is the first to provide a comprehensive and up-to-date analysis of the post-reform FDA Center for Biologics Evaluation and Research and its new licensing process for therapeutic recombinant DNA-derived products and in vivo monoclonal antibody products. This module covers the complete U.S. biotech product approval process, from preclinical testing to post marketing regulatory requirements.

### Biography

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## Adverse drug reaction-causality assessment scales

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Adverse drug reaction according to WHO is defined as "Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function". Adverse drug reaction (ADR) monitoring involves following steps

1. Identifying adverse drug reaction (ADR).
2. Assessing causality between drug and suspected reaction by using various algorithms.
3. Documentation of ADR in patient's medical records.
4. Reporting serious ADRs to pharmacovigilance centers /ADR regulating authorities. For the assessment of causality between drug and suspected ADR, various causality assessment scales been used. Most commonly used causality assessment scales are Naranjo ADR probability scale and WHO -UMC causality categories. These causality assessment scales will be displayed and discussed during this poster presentation.

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