UDIBI
UNIDAD DE DESARROLLO E INVESTIGACION EN BIOPROCESOS

Approval and Registration of Biotherapeutics in Mexico

Emilio Medina-Rivero
Technical-Scientific Director
UDIBI-ENCB-IPN

The National Academies of | SCIENCES ENGINEERING MEDICINE

COMMITTEE ON STRONGER FOOD AND DRUG REGULATORY SYSTEMS ABROAD

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About us

UDIBI-IPN, Third party Lab of COFEPRIS

Services

Consulting

Research & Development

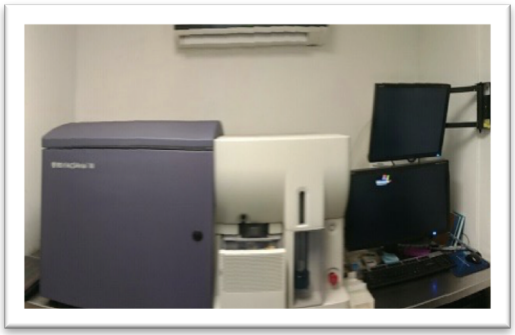
Laboratorio Nacional de CONACyT

Experiencia regulatoria Nacional e Internacional

Infraestructura multicéntrica y multidisciplinaria

Experiencia académica-empresarial a lo largo de la cadena para la innovación

Physicochemical and functional characterization



Our team

Dra. Mayra Pérez
Excecutive Director

Dr. Juan C. Almagro
Innovation Director

Dr. Carlos López
Operations Director

Dr. Emilio Medina
Technical-Scientific Director

frontiers in Medicine

POLICY AND PRACTICE REVIEWS
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Regulatory Pathway for Licensing Biotherapeutics in Mexico

Carlos A. López-Morales[1], Alejandra Tenorio-Calvo[1], Rodolfo Cruz-Rodríguez[2], Julio Sánchez y Tepoz[3], Lahouari Belgharbi[3], Sonia Mayra Pérez-Tapia[1] and Emilio Medina-Rivero[1*]*

[1] Unidad de Desarrollo e Investigación en Bioprocesos, Escuela Nacional de Ciencias Biológicas, Instituto Politécnico Nacional, Ciudad de Mexico, Mexico, [2] Colegio Nacional de Químicos Farmacéuticos Biólogos México AC, Ciudad de Mexico, Mexico, [3] Comisión Federal para la Protección contra Riesgos Sanitarios, Ciudad de Mexico, Mexico

Biotherapeutic products which are derived from living organisms using recombinant DNA technology significantly contribute to the progress in the treatment of life-threatening and chronic diseases. The worldwide sale of biological drugs in 2016 was near US $263,700 million. In Latin America, where monoclonal antibodies market was worth US $7000 million, being Mexico the second largest market. Approval is one of the key aspects which influences the market of medicinal products, thus it is responsibility of the regulatory authority to establish a regulatory framework that ensure safety and efficacy of the products, and it is responsibility of the applicants to provide a high quality

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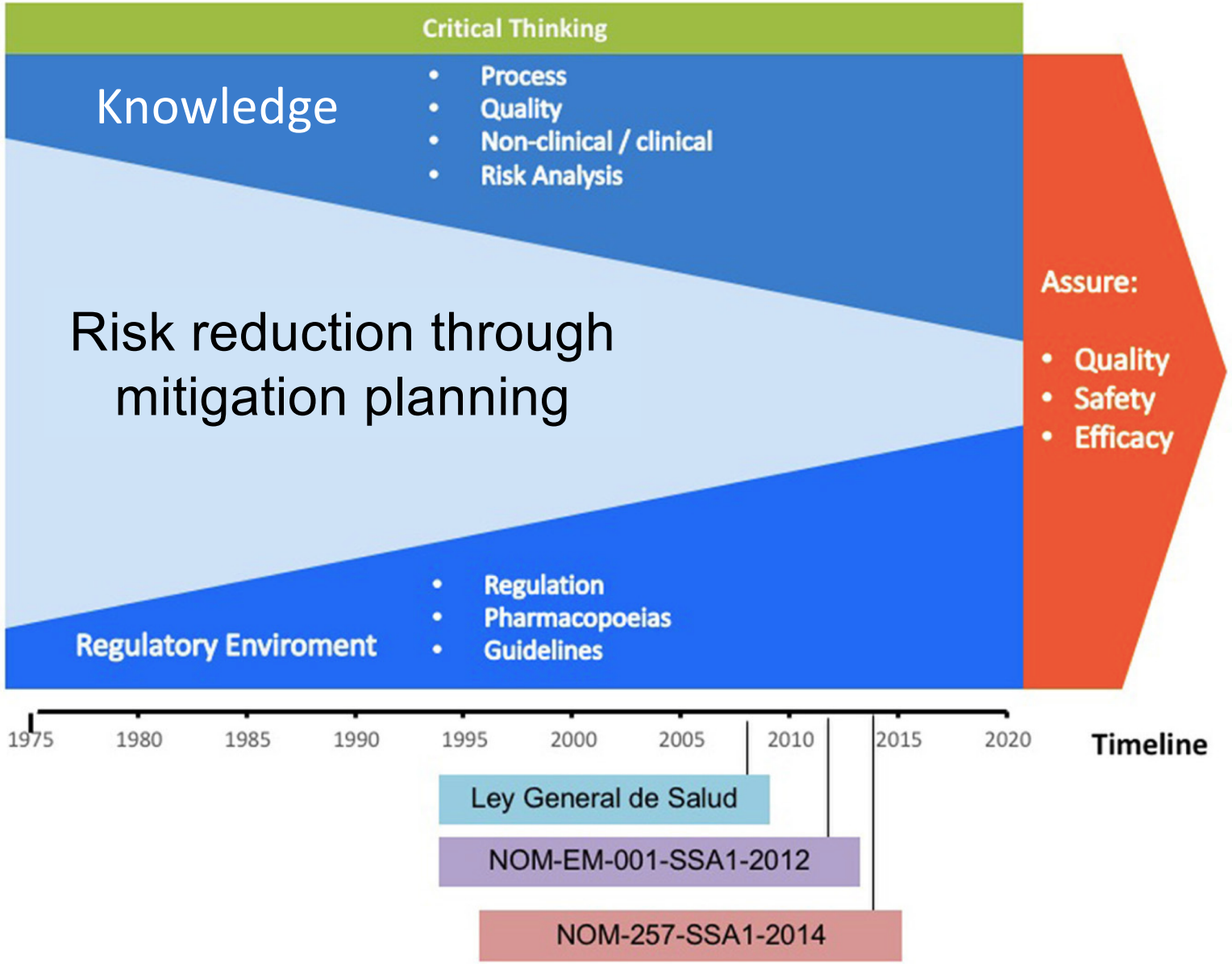
Edited by:
Jan Willem Van Der Laan, Medicines Evaluation Board, Netherlands

Knowledge and criteria for biotherapeutic approval during time



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Framework for biotherapeutics in Mexico

Regulation	Title
NOM-012-SSA3-2012	Establishing criteria for execution of research projects for health in humans.
NOM-059-SSA1-2013	Good manufacturing practices for drug product.
NOM-072-SSA1-2012	Labeling of drug and herbal products.
NOM-073-SSA1-2005	Drug substance and drug product stability.
NOM-164-SSA1-2013	Good manufacturing practices for drug substance.
NOM-177-SSA1-2013	Requirements for authorized third parties that perform interchangeability tests. Requirements to conduct comparability studies. Requirements for authorized third parties, research centers or hospital institutions that perform comparability tests.
NOM-220-SSA1-2016	Pharmacovigilance operation.

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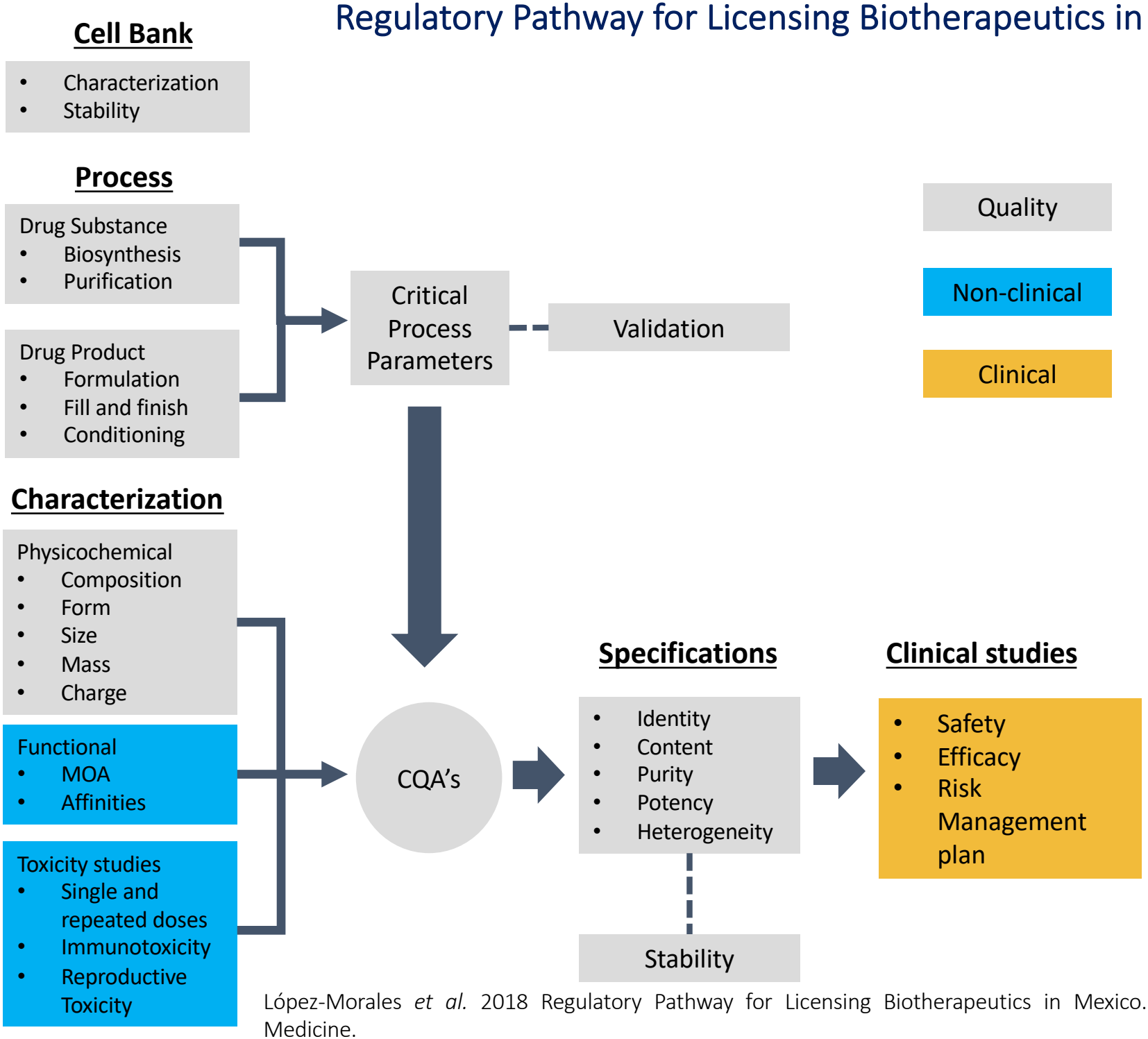
Regulatory Pathway for Licensing Biotherapeutics in Mexico



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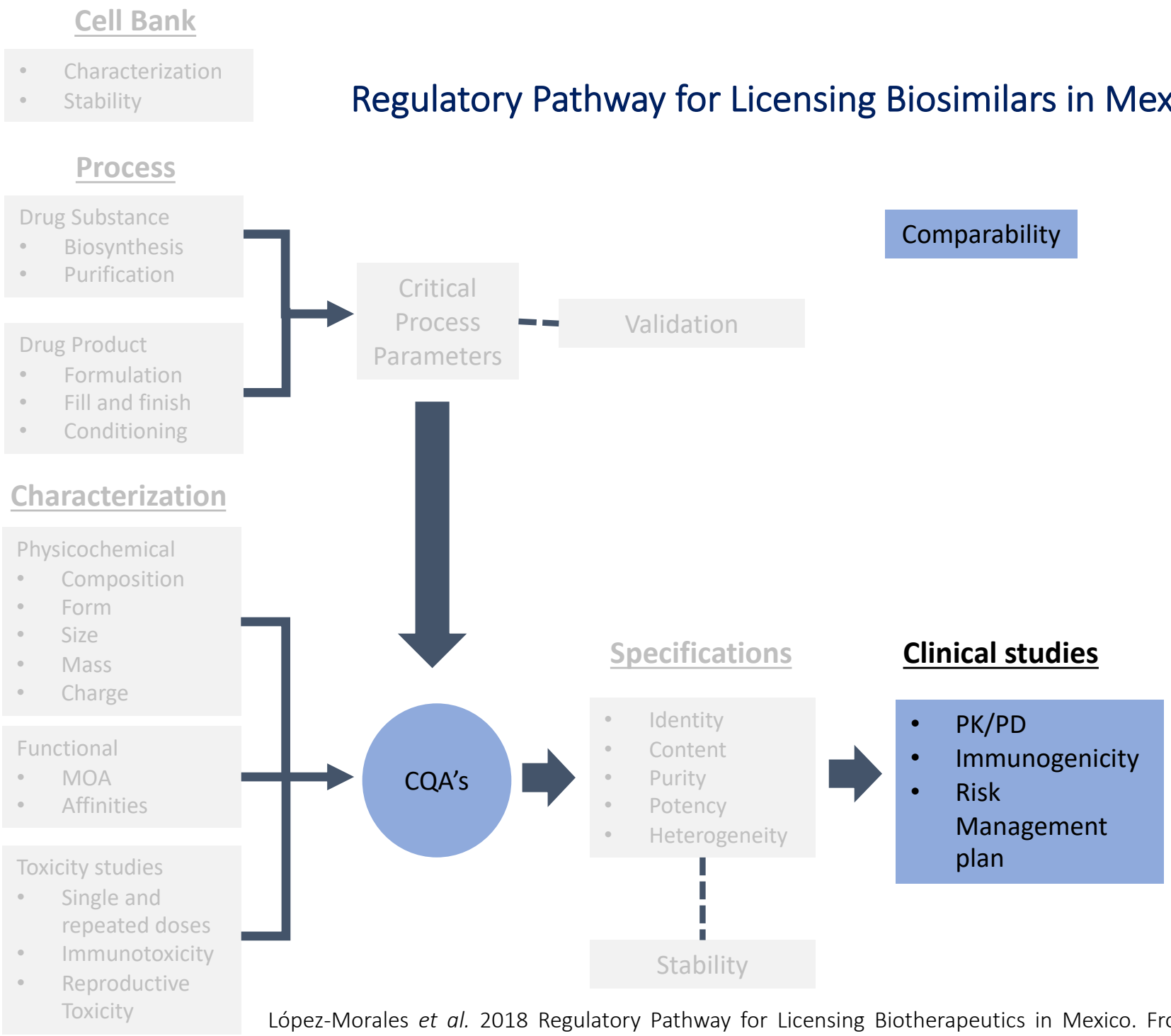
Regulatory Pathway for Licensing Biosimilars in Mexico



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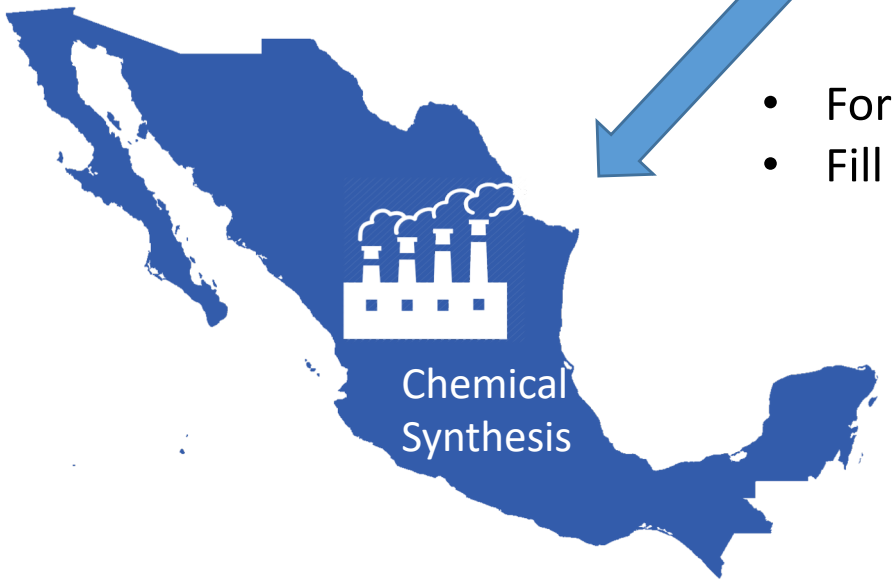
Pharmaceutical industry in Mexico

Drug product

Drug Subtance

Commecialization



- Formulation
- Fill & Finish

Opportunities for the evaluation of biotherapeutics

Close the gap in knowledge and technology

How?

- National and transnational investment
- Local Technological development for biotherapeutics
- Academy-Industry-Government international linkage

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THANK YOU!

Emilio Medina-Rivero
Technical-Scientific Director
UDIBI-ENCB-IPN
emilio.medina@udibi.com.mx

Sonia-Mayra Pérez Tapia
Exeutive Director
UDIBI-ENCB-IPN
sperezt@ipn.mx
mayra.perez@udibi.com.mx

Escuela Nacional de Ciencias Biológicas
Prolongación de Carpio y Plan de Ayala S/N
Col. Santo Tomás
México. DF
+(52) 5729600000, ext 62543, 62591

udibi.com.mx ***udimeb.com.mx***