Vaccine Regulatory Requirements in Brazil

Marcelo Mario Matos Moreira
General-Manager of Biological Products, Blood, Tissues, Cells and Organs – GGPBS

Training for professionals of the vaccine industry
July, 10th 2015
To protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance. This mission must be carried out in coordination with states, municipalities and the Federal District, according to the Brazilian Health System principles, in order to improve the quality of life of the population.
General Office of Biologicals
Drugs Registration

Agência Nacional de Vigilância Sanitária - Anvisa

Each category has its own specific legislations and requirements
Regulatory acts concerning biological products

- **Law 6360/76**
  - RDC 47/09 e 60/12
  - RDC 71/09, RDC 168/02
  - RDC 234/05
  - RDC 17/10
  - **Package insert**
  - **Import**
  - **Quality control**
  - **Good Manufacturing Practices**
  - **Register**
  - **Post-approval**
  - **Stability**
  - **Label**
  - **Good Manufacturing Practices**
  - **Allergenics**
  - **Probiotics**
  - **Biological products**
  - **Antivenom serums**
  - **Quality control**

- **RDC 46/00**
  - **Blood products**

- **RDC 49/11 e 24/13**
  - **Registration**

- **RDC 50/11 and 25/13**

- **RDC 55/10**
  - **Registration**

- **RDC 60/12**

- **RDC 47/09 e 60/12**
  - **Package insert**

- **RDC 71/09, RDC 168/02**
  - **Label**

- **RDC 61/12**

- **RDC 47/09 e 60/12**

- **RDC 17/10**
  - **Good Manufacturing Practices**

- **RDC 234/05**
  - **Quality control**

- **RDC 38/10**

- **RDC 81/08**
  - **Import**

- **RDC 17/10**
  - **Good Manufacturing Practices**

- **RDC 233/05**
  - **Allergenics**

- **RDC 323/03**
  - **Probiotics**

- **RDC 50/11 and 25/13**
  - **Stability**

- **Ordinance 174/96**
  - **Antivenom serums**
1. Vaccines

2. Hyperimmune sera

3. Blood products

4. Biomedicines:
   - medicines obtained from biological fluids or animal tissues;
   - medicines from biotechnologic procedures
5. Monoclonal antibodies

6. Medicines containing live, attenuated or dead microorganisms

7. Probiotics

8. Allergens
1. Vaccines are immunobiological drugs containing one or more antigenic substances that, when inoculated, are able to induce specific active immunity, in order to protect against, reduce the severity or fight the disease(s) caused by the agent that originate the antigen(s);
1. RDC 55/2010

2. Harmonized requirements for the licensing of vaccines in the Americas and Guidelines for the preparation of application
Dossier must support all evidence for license

1. Legal documentation

2. Vaccine manufacture and quality control documentation

3. Nonclinical and clinical reports
1. Legal documentation

- Licenses, authorizations and certificates

GMP must be assessed by ANVISA’s inspectors
2. Quality

- Manufacturing stages and Quality Control information
- Transport chain validation protocol and report
- Stability studies protocol and report
- Description of the used strains
- Description of the master and working seed batches of the virus and cell lineage used
- Description of the master and working cell bank system
3. Safety and Efficacy

- Report of all nonclinical studies
- Protocols and reports of the clinical studies, phases I, II and III
- Pharmacovigilance plan and a risk minimization plan
Guideline for Elaboration of Clinical Study Reports

http://s.anvisa.gov.br/wps/s/r/lg
Drug Approval and Refusal Letters
Post approval changes
Post approval changes

Level 1 change (minor changes)
Do and Tell

Level 2 change (moderate changes)
Tell and Do

Level 3 change (major changes)
Tell and Wait
94 vaccines licensed in Brazil

05 Brazilian Manufacturers

- Fundação Ataulpho de Paiva
- Fundação Ezequiel Dias – FUNED
- Fundação Oswaldo Cruz/Bio-Manguinhos
- Instituto Butantan
- Instituto de Tecnologia do Paraná – TECPAR
Brazilian Scenario

Agência Nacional de Vigilância Sanitária - Anvisa

Brazilian Manufactures

14 vaccines

International Manufacturers

80 vaccines
<table>
<thead>
<tr>
<th>Rank</th>
<th>Challenge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dengue vaccine license</td>
</tr>
<tr>
<td>2</td>
<td>tOPV to bOPV(_{1&amp;3})</td>
</tr>
<tr>
<td>3</td>
<td>Pre-qualified PAHO Vaccines</td>
</tr>
</tbody>
</table>
- Brazil, Resolution RDC n° 55, December, 16th, 2010, Anvisa
- Brazil, Resolution RDC n° 50, September, 20th, 2011, Anvisa
- Brazil, Resolution RDC n° 49, September, 20th, 2011, Anvisa
- Brazil, Law n° 6360, September, 23th, 1976
- www.anvisa.gov.br
Thank you

Agência Nacional de Vigilância Sanitária - Anvisa

Acknowledgments

GPBIO and GSTCO Staff
SUMED/ANVISA

Contacts

phone: +55(61)3462-5593
E-mails: ggpbs@anvisa.gov.br
produtos.biologicos@anvisa.gov.br
sangue.tecidos@anvisa.gov.br

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área especial 57 - Lote 200
CEP: 71205-050
Brasilia - DF
Phone: +55(61)3462 6000

www.anvisa.gov.br
www.twitter.com/anvisa_oficial
Anvisa Atende: 0800-642-9782
ouvidoria@anvisa.gov.br