

Session 8

Panel Regulator-Developer Dialogue

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Regulatory systems

- Argentina: CONABIA – Previous Consultation Instance (ICP)
- Brazil: CTNBio – Previous consultation procedure
- USA: FDA Center for Veterinary Medicine – Application for IGAs in animals
- Future perspectives:
 - Kenya: National Biosafety Authority - Early Consultation
 - Nigeria: National Biosafety Management Agency – Application for gene editing



General Aspects

- All systems allow for consultation on products under development or even hypothetical products before development
- Same process applied to plants, microorganisms and animals
 - Except for the US
- Focused on the final **product**, rather than the process, but takes into account the process
- Case-by-case, based on scientific evidence, Risk-based analysis



General Aspects

- Open communication channels
 - In the US it involves an open and permanent dialogue for the duration of the evaluation
 - In Brazil and Argentina communication is maintained via correspondence, but there are direct lines of communication
- Regulators can require clarifications, additional information or additional data before giving their outcome
- “New combination of genetic material”

Personal highlights

- Transparency
- Building a “long term relationship”
- Open communication channels with the company: make yourself available



Highlights from the process - Timeframe

- Argentina: 2 months
- Brazil: 2 to 3 months
- USA: about 6 months

- Fast and efficient

- In all cases the process will take longer when confidentiality is required



Developing the application

- Try to put yourself on the regulator's shoes
- Use a problem formulation and Risk assessment mindset during the formulation of your document
- Consider the Audience
 - Who are you writing for
 - What are their worries/perceptions
 - How your message is best conveyed
- State before hand:
 - Possible hazards identified
 - Control methods developed
 - Risk management strategies already in place or being considered





Recommendations

- Do not make assumptions
 - Define terms, methods and processes in a clear and concise way
 - Be thorough but brief
 - Avoid redundancies
- Make sure is understandable for non-animal scientists
 - People from other expertises should be able to understand the product and process
 - Give a clear context of the problem it solves inside the animal production chain
 - Use visual aids: pictures, graphs, visual summaries

Confidential Information

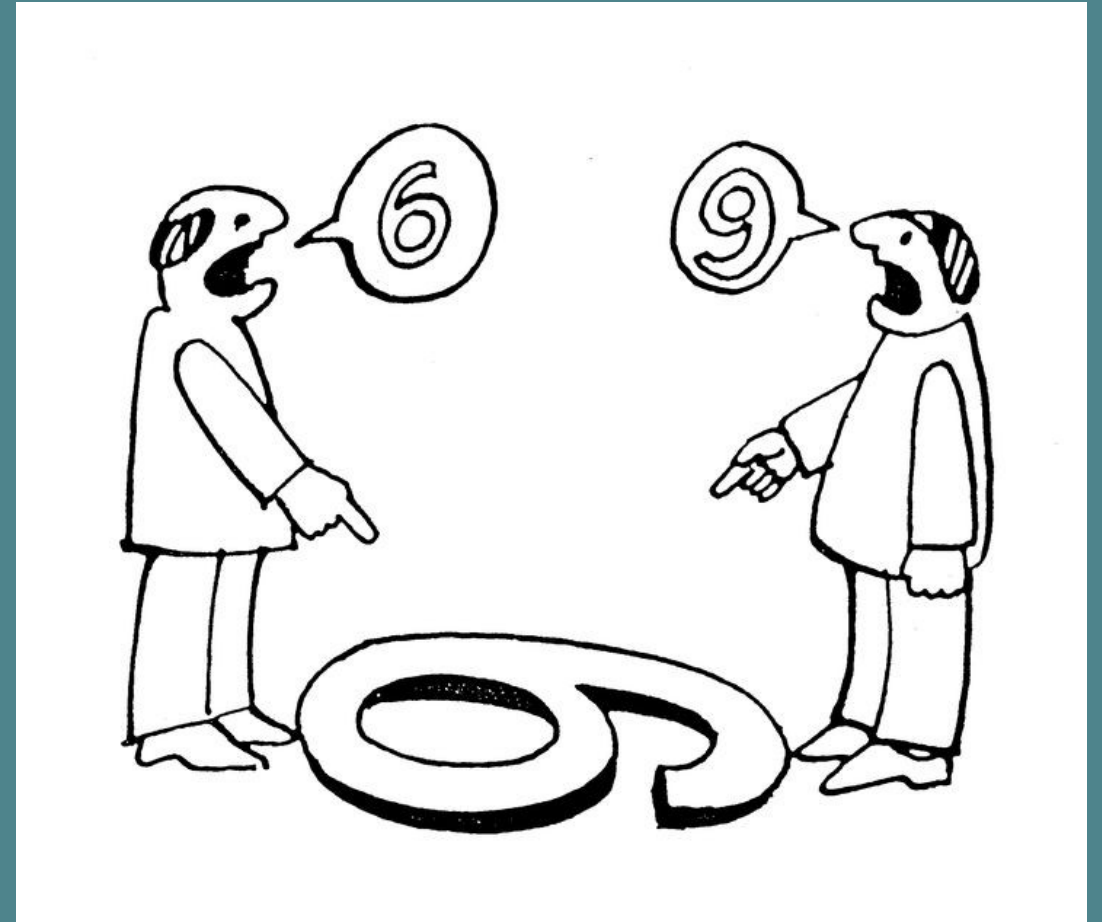
- Try to avoid confidentiality requirements
- ONLY WHEN necessary
- ONLY WHAT is necessary

- The less you need to keep a secret, the better the dialogue will flow
 - Choose wisely



Final Recommendations

- Actively take part in trainings, educational sessions and stakeholder engagement
 - Listening to other people's take on your products can help identify perceptions/fears/doubts
- Do not miss the opportunity to explain first hand your development
- Put it in context
- Adjust to your audience



THANK YOU



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