



# Red tape hurdles

## “le parcours du combattant”

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# “Foresight is the key element “

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- Don't forget that the best innovative project will never be used if there is no regulatory approval
- Importance of the quality and reproducibility
- Step by step development lead to a step by step approval



# Regulatory aspects

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- Legislation framework is often behind
- Different approach of the countries
- Viral safety on biotech product
- Pre-clinical request
- Clinical request in relation with target population optimum patient's number

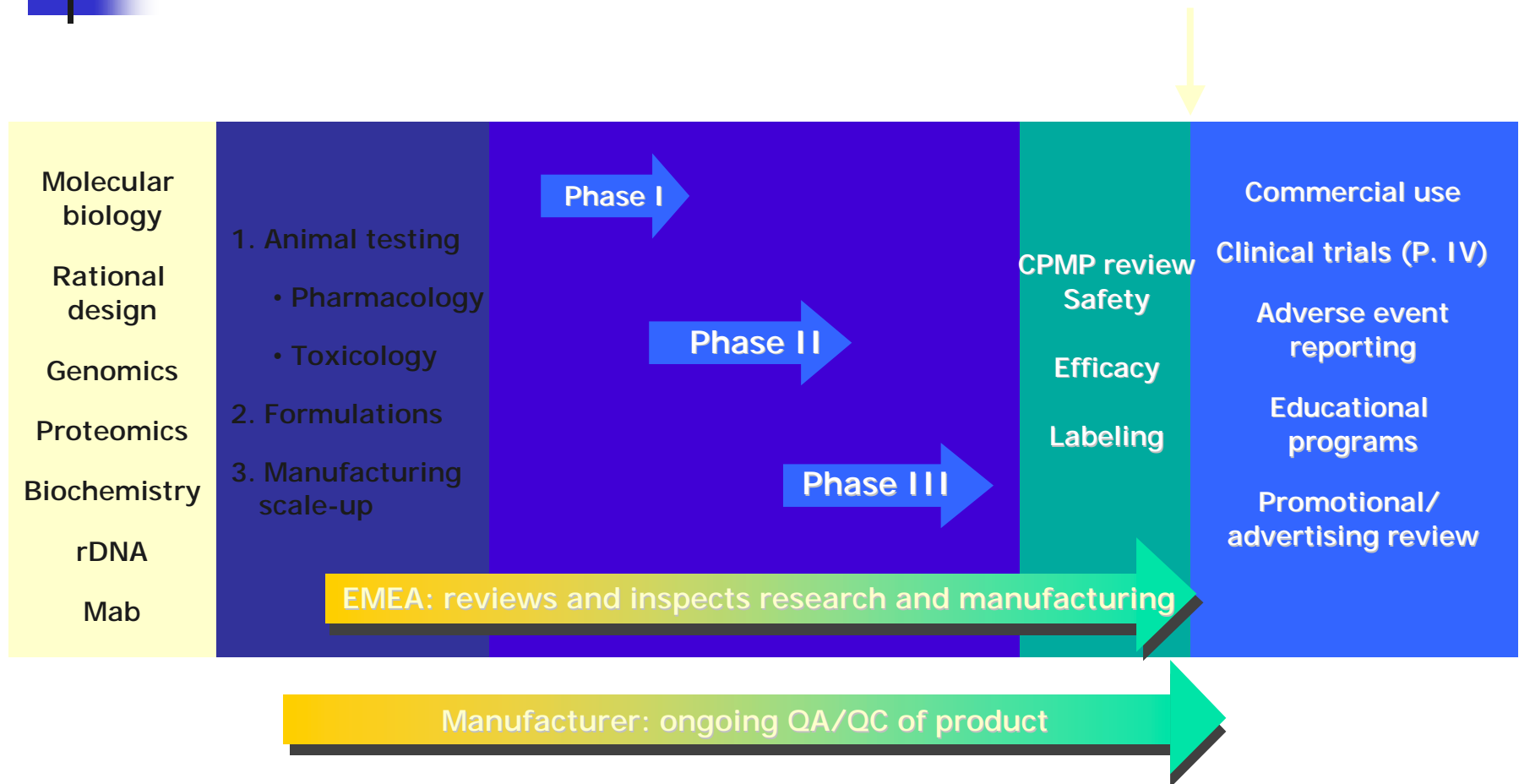


# Other aspects to keep in mind

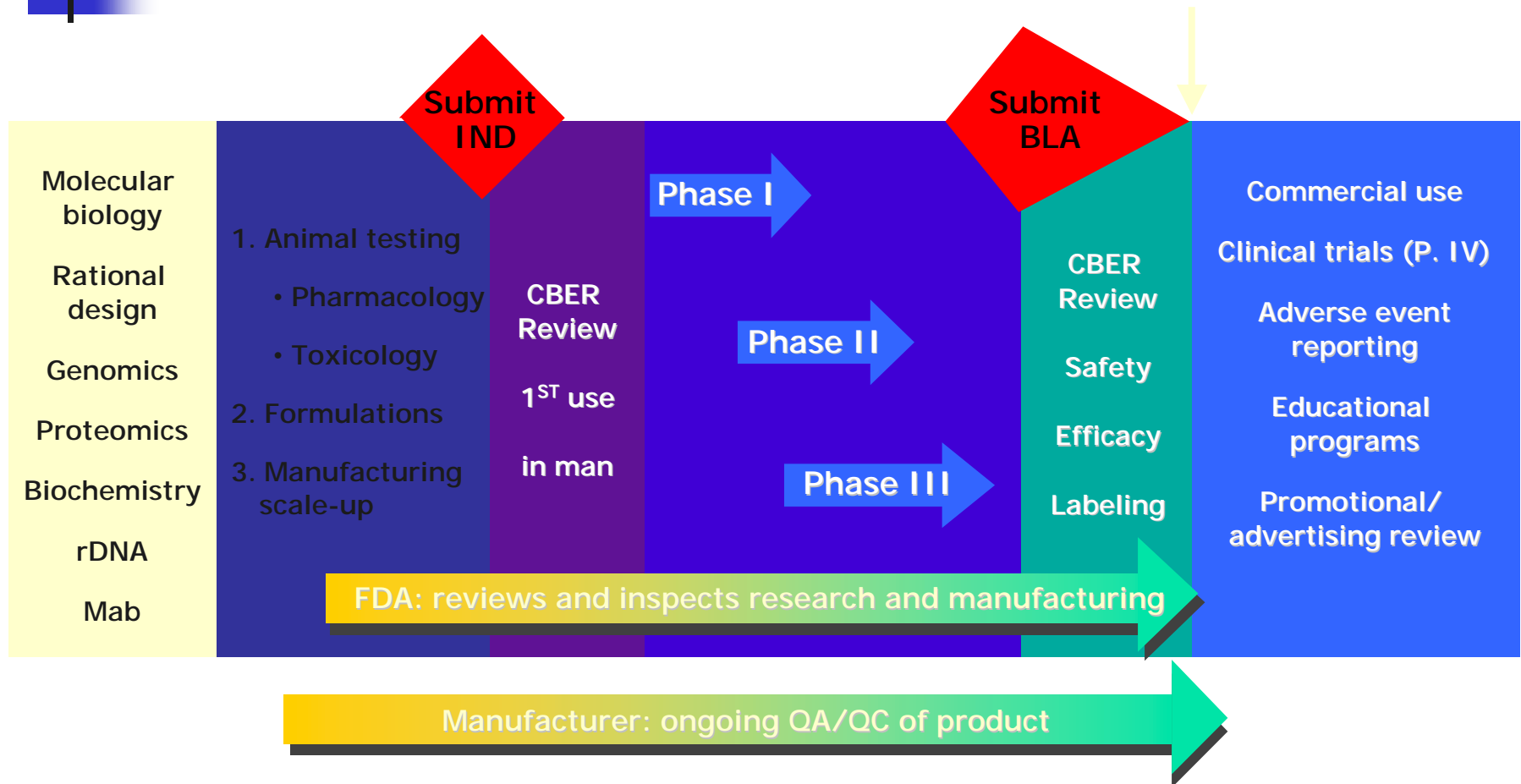
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- Scientific advice
- QA and QC
- Changes in manufacturing process
- Immunogenicity
- CTD with regional difference for biotech
- Fast track for FDA

# Steps in Drug Development EUROPE



# Steps in Drug Development USA





# EMEA

# vs

# FDA

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- Scientific advice
  - Active comparator
  - External expertise
  - MA delay 12 to 18 months
  - Local specificity
    - Price and reimbursement
    - Commercialization
    - Promotional activity
- Scientific approval
  - Efficacy against placebo
  - Internal expertise
  - Fast track for important drugs
  - A unique MA



# Key learning

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- New technology build the regulatory framework
- Transparency at all the steps
- Efficacy and safety are the key words
- Consensus is always a challenge
- French expertise on biotech



# For more information

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The logo graphic consists of a vertical black line on the left, intersected by a horizontal black line. To the left of the vertical line are three overlapping squares: a yellow one at the top, a red one in the middle, and a blue one at the bottom. The text 'Amgen S.A.S' is written in a bold, blue, sans-serif font to the right of the vertical line.

# Amgen S.A.S

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