The Importance of CMC for Bringing Animal Health Phage Products to Market

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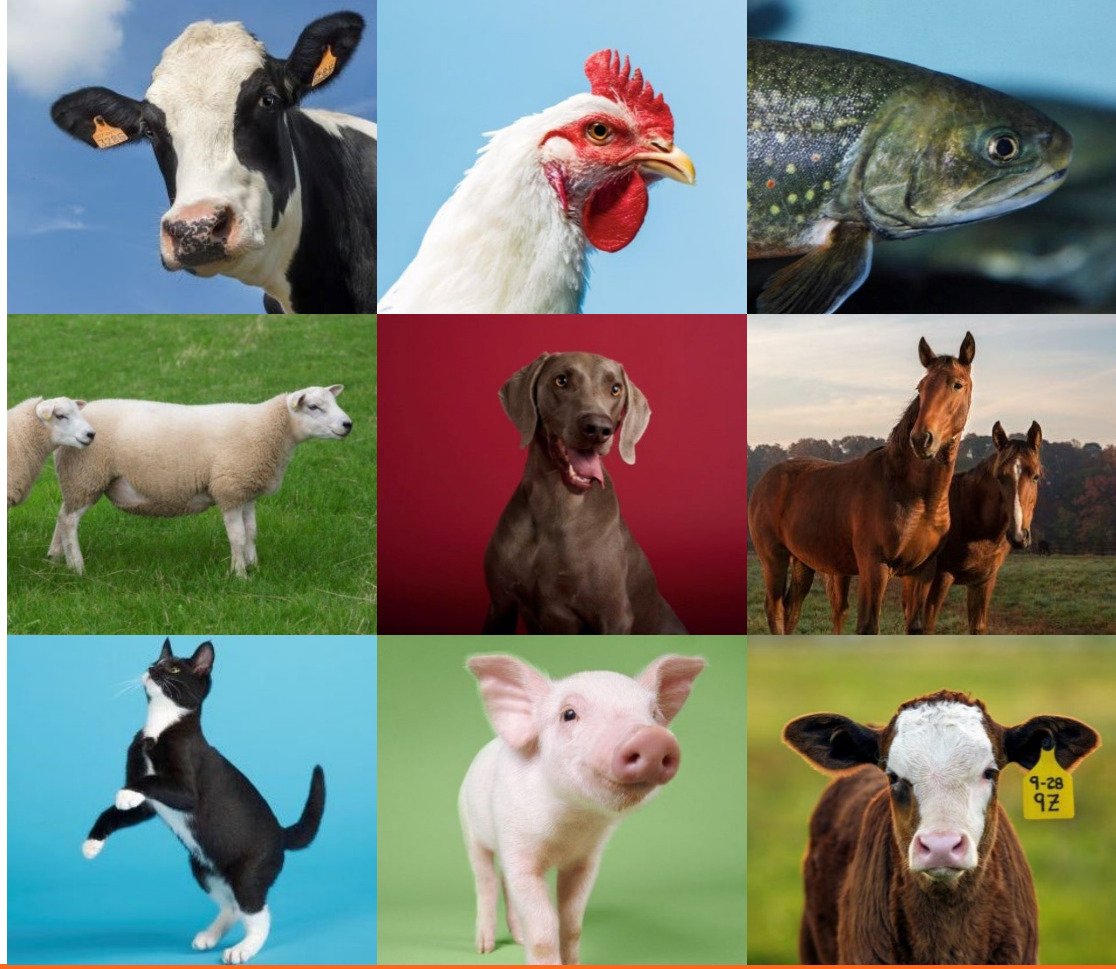

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Importance of Manufacturing in the Drug Development Process

- Manufacturing is one of several key components of a regulatory dossier
  - Efficacy (does it work?)
  - Safety (is it safe?)
  - CMC (Chemistry, Manufacturing, Control) (can you consistently make it to specifications)

- CMC work must start early in the process
  - Pivotal studies are done using final process materials
    - Late Research or Discovery Phase
    - Formulation
    - Specifications for production
    - Final API

  - Phages have some specific challenges in regards to manufacturing
    - Phage cocktails
      - Individual APIs for each phage
      - Combined for final product

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Phage related CMC challenges

- Clostridium phages use as an example
  - Treatment of Necrotic Enteritis in Poultry
  - *Clostridium perfringens*

  - Will necessitate standalone facilities as phage is a potential contaminant
    - Introduction of Phage could put vaccine or pharma product manufacturing at risk
    - Standalone facilities will require a capital investment for production
    - 15-25M USD; 5 years

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Manufacturing Capacity is a major issue

- Global animal populations are large.
  - Beef Cattle: 1.55B
  - Dairy Cattle: 270M
  - Swine: 800M
  - Poultry: 14 (66)B

- Assumptions for a poultry treatment:
  - Prevention claim: continuous daily dosing in feed
  - Phage yield: 1 x 10^{11} PFU/ml
  - Dose: 1 x 10^{6}
  - Number of Dose/Liter: 1x10^{8}
  - 50% global market penetration: 7 billion doses/d x 365=2.5T doses
  - 25K Liter capacity
  - Continuous flow or high throughput systems may be options

Joao et al. Biotech Adv. 2021

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