PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

CDMO Sector Perspectives on OMUFA Reauthorization

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The **Pharma-Biopharma Outsourcing Association (PBOA**), founded in 2014, is a nonprofit trade association dedicated to **advancing the regulatory, legislative, and general business interests of *Contract Development and Manufacturing Organizations (CDMOs)*** and other contract service providers.

Today, PBOA has **50+ member companies, along with 23 affiliate members**, who provide the technologies and services that help the pharma, biopharma, and consumer health industry **develop, manufacture, and package drugs, vaccines, OTC products, and other treatments safely, reliably, and cost effectively**

CDMOs are central to success of the biopharma and consumer health industry

- We enabled **development of >80% of NMEs approved** by the FDA and EMA over last decade
- We **produced >55% of NMEs approved** since 2017 – **including COVID-19** vaccines and treatments authorized under EUAs
- Overall, we **produce 2 of every 5 doses** of drugs, vaccines, and OTC products dispensed in western markets
- We play a **critical role in early pharma innovation** by enabling emerging biopharmas - ~75% of active pipeline
- We supply ANDA-/monograph-based OTCs, nutritionals
- We **employ ~35,000 across ~170 US facilities**
- Our **FDA inspection Form 483 issuance rates are comparable**[1] with branded company captive facilities
- We produce **more than a dozen modalities across all routes** of administration (e.g. small molecules, proteins, gene/cell)
- We do not own, set prices for, or distribute drugs[2]

Note: all statistics represent PBOA members only

1 Versus captive sterile and non-sterile facilities on average, source: Redica FDAZilla

2 Certain members are divisions of filing-holders or own NDA/BLA/ANDAs

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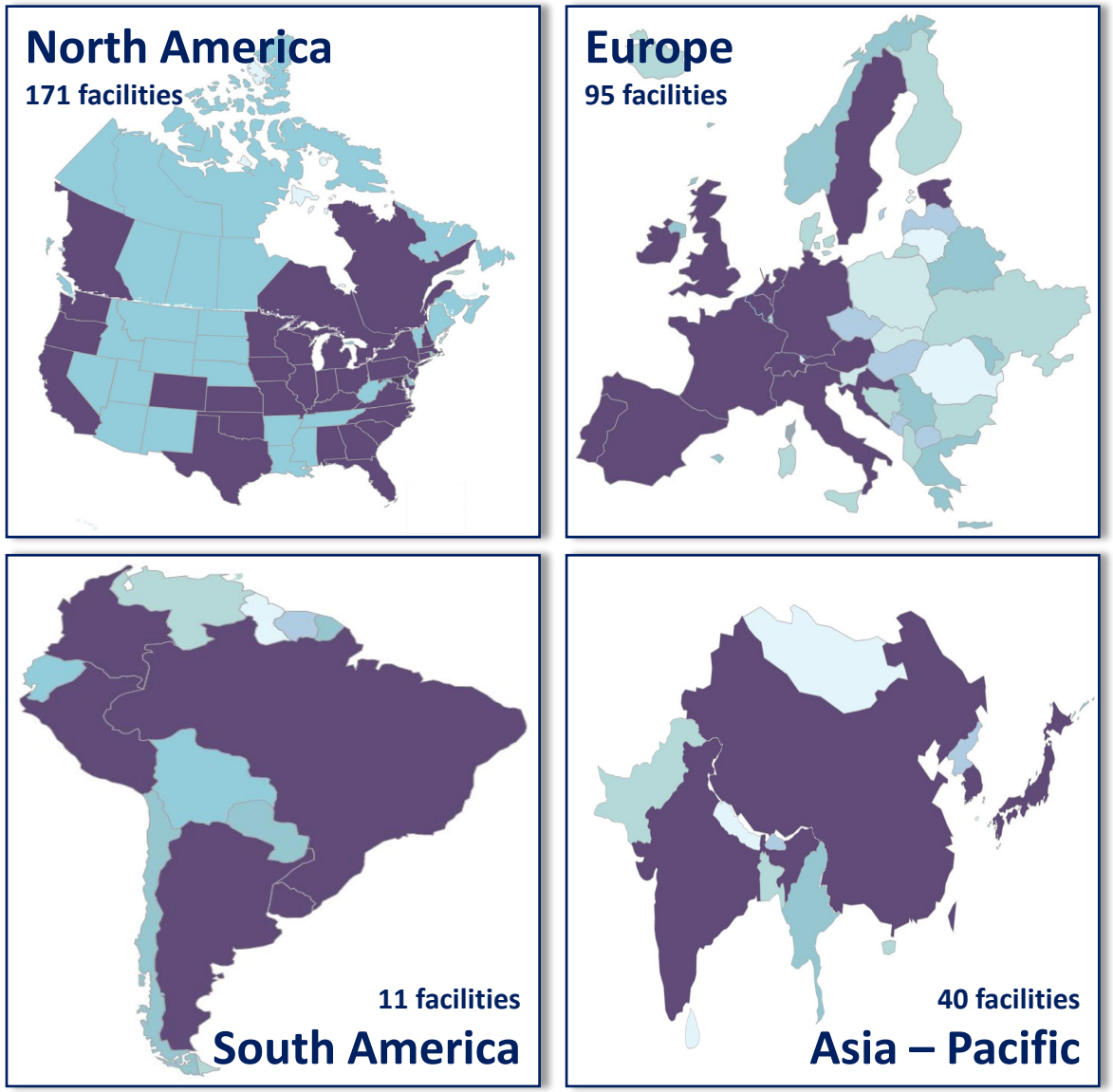
PBOA members support global drug development & supply



- More than **300 operating facilities** around the globe, plus other offices and labs
- **Finished dose facilities** cover all dose formats, including ~80 injectable fill/finish
- **API facilities** include chemicals (50), proteins (40), and gene and cell (24)
- **~85%** of commercial sites **registered w/ FDA, EMA, or MHRA** *or pending such*
- Global **employment ~50,000+**
- A site may be the **sole source** of a product, a sole external source, or part of a multi-site sourcing network

Not shown: Facilities in middle east, Australia, Egypt, South Africa, Singapore, and Puerto Rico

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PBOA Members Impacted by Most User Fee Programs

- PBOA members are currently involved in **most of FDA's User Fee programs**: PDUFA, GDUFA, BSUFA, ADUFA, MDUFA, OMUFA
- **Key design principles** for user fee-driven programs, including enhancements thereto:
  - The **party who receives the economic benefit should pay the fees**, both for the program and any enhancements thereto
  - The fee should fully recover the **actual or best estimate of cost** of services provided, unless there's a public policy reason to do otherwise (e.g. effective time reporting, etc.)
  - Ability to implement; available data/IT systems to effectively support; auditability/transparency
- **Real downside impact** for PBOA members of mis-aligned fees and value: layoffs; reduced capacity available (supply disruption/shortage risk?); reduced ability to invest in innovation, capacity, new jobs

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PBOA Perspectives on OMUFA Reauthorization

- PBOA **continues to support OMUFA's fundamental goals** and approach, and recognizes FDA's progress despite the impacts of the pandemic
- The pandemic and resulting pullback in consumer spending has impacted OTC and nutritional supplement demand – causing a **contraction of available CDMO supply** via facility layoffs/closures, insourcing, geopolitical supply chain issues
- As program focus turns to OMORs, we will seek **transparency of OMOR efforts and outcomes**, as we've seen with other maturing UFA programs
- **Effectively redeploy and fully leverage OMUFA-funded resources** to support evolving program, before seeking to expand staffing
- Align payment of negotiated increases in fees to **those parties receiving the economic benefits therefrom**

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