



PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

A SEAT AT THE TABLE

The **Pharma & Biopharma Outsourcing Association** gives CDMOs a voice on the Regulatory, Legislative and Business issues that matter most.

We bring the CDMO sector's message to FDA, Capitol Hill, and the greater bio/pharma industry, by advocating for our members in the US and abroad on user fees, regulations and laws, trade issues, and more.

PBOA also gives our members opportunities to interact with their peers, share best practices, and become a stronger industry in support of their customers and patients.

JOIN **PBOA** TO GAIN A SEAT AT THE TABLE

FOR INFORMATION REGARDING PBOA MEMBERSHIP TERMS AND ORGANIZATIONAL GOALS,
visit www.pharma-bio.org or contact **PBOA President Gil Roth** at 201-788-7994 or gil.roth@pharma-bio.org



PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

CMOs and CDMOs deserve a seat at the table.

Join the only trade association built to represent ***YOU!***

BENEFITS OF MEMBERSHIP IN PBOA INCLUDE:

REGULATORY/LEGISLATIVE

- PBOA members learn about new regulations, guidances, and legislative trends *FIRST*.
- PBOA meets with key Congressional offices and Directors of CDER, OPQ, OGD, ORA and other FDA offices to build awareness of CMO/CDMO issues.
- PBOA's relationships with FDA gives our members unprecedented "troubleshooting" resources.
- PBOA drastically reduced the GDUFA II facility fee burden for CDMOs through negotiations with FDA and industry, and protected the CDMO sector in GDUFA III negotiations. PBOA also negotiated a "CMO carveout" tier for the OTC Monograph User Fee (OMUFA).
- PBOA advocates for CDMO interests by lobbying members and staff of Congress, testifying at Congressional hearings, participating in FDA public meetings, submitting comments to FDA dockets, and holding face-to-face meetings between PBOA members and FDA personnel.
- We identify trends and concerns among CDMOs through our Working Groups, covering Quality, Serialization, Drug Shortages, ESG, Opioids, Canadian Affairs, and more.

ALLIANCES

- PBOA works with other trade associations and cross-industry consortia to carry our message throughout industry, represent CDMO interests in areas such as Quality Metrics and Drug Shortages,

and build stronger relationships between CDMOs and their bio/pharma customers.

EXPOSURE

- PBOA organizes and participates in panels and presentations featuring our member companies. PBOA has organized member-driven sessions at INTERPHEX, BIO, PDA, TraceLink NEXUS, AAM, and the PDA/FDA Joint Regulatory Conference.
- PBOA sponsors the annual CMO/CDMO pavilion and reception, and organizes speakers and panel at INTERPHEX.
- Our weekly e-newsletter circulates outsourcing news and policy issues throughout the industry, while PBOA stories and member news are covered in major industry media.

NETWORKING

- PBOA holds an annual members-only Meeting & Conference with participation from FDA speakers and other expert presenters.
- Our working groups meet by teleconference and in person to exchange best practices and learn from each other, and their members also meet face-to-face with key FDA policy-makers.
- Member companies meet at informal networking events and board meetings.
- Affiliate Members provide exclusive offers for products and services to our CDMO members.

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SUSTAINING MEMBERS

Afton Scientific
Avara Pharmaceutical Solutions
Cambrex
Catalent Pharma Solutions
INCOG BioPharma Services
Jubilant HollisterStier
Kindeva Drug Delivery
Pfizer CentreOne
Piramal Pharma Solutions
Thermo Fisher Scientific
TriRx Pharmaceuticals

GENERAL MEMBERS

Adare Pharma Solutions	J-STAR Research / Porton
Ajinomoto Bio•Pharma Services	Lifecore Biomedical
Alcami	LTS - Lohmann Therapie-Systeme
ApiJect Systems	Lubrizol Life Sciences - Health
Archimica	Pace Analytical Life Science
Avid Bioservices	PCI Pharma Services
BioMedica Diagnostics	Pii - Pharmaceuticals International, Inc.
Bioworksops	Renaissance Lakewood
Bora Corp.	Selkirk Pharma
CMIC CMO USA, Inc.	Sever Pharma Solutions
Coating Place, Inc.	Sharp
Cytovance Biologics	Singota Solutions
DPT, a Viatrix Co.	Societal CDMO
Element	Sovereign Pharmaceuticals
Grand River Aseptic Manufacturing	Tjoapack
Groupe PARIMA	Vetter Pharma
HIKMA	Woodstock Sterile Solutions
InterBiome	

AFFILIATE MEMBERS

Apprentice.io • Bandwidth Solutions • CAI • CM Plus • Datex • Global Pharma Consulting
INTERPHEX • Iwata Label • MasterControl • Namikos Co. • NoviSystems • PharmaBioSource
PQE Group • ramarketing • SafeBridge Consultants • SCORR Marketing • Tomita Pharma •
TraceLink • Veeva Systems • Waters Corp. • White Owl Global Consulting • Vector Partners



*Advancing the regulatory, legislative, and general business interests
of the pharmaceutical and biotech services community*

MEMBERSHIP APPLICATION FORM

PROPOSED MEMBERSHIP CATEGORY

*Please check just **one** of the following boxes*

- ☐ General Member
- ☐ Sustaining Member (*incl. nomination for 3-year term on PBOA Board of Trustees*)
- ☐ Affiliate Member (*for companies that provide goods/services to CMO/CDMOs*)

NAME AND CONTACT INFORMATION OF PROPOSED MEMBER COMPANY

Name of company:

Name of individual representing company:

CONTACT INFORMATION

Street:

Bldg./Ste. #:

City:

State:

Zip:

Tel:

Fax:

E-mail:

DUES

General Member

*Please check just **one** of the following boxes, based on your firm's annual contract services revenue*

- | | |
|--|--|
| <input type="checkbox"/> less than \$5 million = \$5,000/year | <input type="checkbox"/> \$50 million to \$100 million = \$12,500 |
| <input type="checkbox"/> \$5 million to \$20 million = \$7,500 | <input type="checkbox"/> \$100 million to \$250 million = \$15,000 |
| <input type="checkbox"/> \$20 million to \$50 million = \$10,000 | <input type="checkbox"/> more than \$250 million = \$20,000 |

Sustaining Member

- ☐ \$25,000 first year, then General Member level after (check this box, and one box above)

Affiliate Member

- ☐ Contact me with information about Affiliate Member dues

Signature

Date

Name

Title

Please complete this form and e-mail it to gil.roth@pharma-bio.org or mail it to the address below