

PBOA Strategic Plan – 2020 thru 2024



Our Vision Framework

Our Vision

PBOA envisions a world where CMO/CDMOs are valued by their customers, have an essential voice in legislative and regulatory affairs, and are recognized as crucial elements of the global Supply Chain

Our Mission

To help patients worldwide by enabling our FDA-regulated members to develop and deliver effective, quality medicines on behalf of their customers

Our Guiding Principles

- Manufacturing and Scientific Expertise is a core value of our member companies
- A culture of Quality and Regulatory Compliance that drives decision making
- Our membership is diverse and inclusive. We represent a significant portion of the CMO/CDMO sector.
- We are responsive, flexible and influential



PBOA Strategic Plan – 2020 thru 2024

Our Vision Framework

Our Strategic Goals – 2020 thru 2024

1. Establish PBOA as the public voice of the CMO/CDMO Sector
2. Advance policy and advocate on behalf of members with legislators and regulators
3. Create collaborative environment via Working Groups, Conferences, and with other Associations and Stakeholders
4. Evolve and increase the reach and breadth of PBOA
5. Evolve and improve the leadership, organizational structure and effectiveness of PBOA



PBOA Strategic Plan – 2020 thru 2024

Our Strategic Goals for 2020 - 2024

Strategic Goal #1: Establish PBOA as the public voice of the CMO/CDMO Sector

Strategic Initiatives

- 1.1** Increase visibility with US Federal Legislators through obtaining audiences and participating in legislative meeting opportunities that can showcase the purpose of PBOA
- 1.2** Increase interactions with FDA and other key Health Ministries
- 1.3** Seek opportunities for positive messaging about PBOA & CDMO sector through Industry Publications and other general interest and business media outlets. Seek opportunities to increase awareness of importance of CMO/CDMO Industry with healthcare stakeholders and general public, and build confidence in outsourcing sector
- 1.4** Identify and collectively prioritize members' key issues and strategic goals

Key Performance Measures

- Number of key meetings with Legislators
- Number of key interactions with FDA and other Ministries of Health
- Number of interaction with Federal Agencies (DHS, FEMA, etc.)
- Number of published references to PBOA



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Our Strategic Goals for 2020 - 2024

Strategic Goal #2: Advance policy and advocate on behalf of members with legislators and regulators

- Identify key issues and objectives through regular interactions with members
- Stay ahead of potentially adverse impacts by monitoring situations and lobbying
- Increase visibility to regional and state issues to further support member needs

Strategic Initiatives

- 2.1 Establish and annually revise policy guidance document
- 2.2 Assess legislative support in Washington – improve visibility to members
- 2.3 Be selective and pursue aggressively those policy areas of most importance to our members
- 2.4 Recommend path forward for State issue identification and influence
- 2.5 Identify members' ex-US issues that leverage PBOA experience

Key Performance Measures

- Annual report of overall effectiveness of Federal Legislation support mechanism
- Recommendation and acceptance of State and Regional support concepts
- Member satisfaction survey



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Our Strategic Goals for 2020 - 2024

***Strategic Goal #3:** Foster a compliant environment for developing policy recommendations and sharing best practices by member companies via Working Groups, Conferences, and collaborations with other Associations and Stakeholders*

Strategic Initiatives

- 3.1** Re-evaluate Working Group Structure with compliance code of conduct. Create and modify as appropriate to meet objectives of member companies
- 3.2** Continue to evolve the PBOA Conference concept. Increase attendance and relevance every year
- 3.3** Identify key issues for collaboration with other industry associations which overlap the goals of PBOA. Establish meaningful partnerships
- 3.4** Increase variety of opportunities for member companies to interact
- 3.5** Assess CDMO crisis resilience and policy responses/recommendations

Key Performance Measures

- Attendance at PBOA Annual Conference
- Number of interactions with other Industry associations
- Number of Meetings (Working Group, Board, Special, etc.) with member involvement
- Survey of PBOA responses to COVID-19 pandemic



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Our Strategic Goals for 2020 - 2024

Strategic Goal #4: Evolve and increase the reach and breadth of the PBOA

Strategic Initiatives

- 4.1 Increase the number of Members of PBOA, including Affiliate Members
- 4.2 Consider all adjacent CMO Industries (i.e. Biologic Drug Substance, Cell and Gene Therapy, Specialty API) and tee up for a strategic discussion with Board and Membership
- 4.3 In annual consultation with Board, identify and hold meaningful meetings with Top 10 prospects
- 4.4 Consider serving additional Geographies beyond North America. Set Strategic direction in conjunction with Board and Membership
- 4.5 Develop marketing strategy for PBOA

Key Performance Measures

- Number of PBOA Member Companies
- Number of PBOA Affiliate Companies
- Strategic Discussion about adjacent areas for expansion
- Strategic Discussion about Geographical expansion
- Number of Top 10 Targets identified and contacted



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Our Strategic Goals for 2020 - 2024

Strategic Goal #5: Evolve and improve the leadership, organizational structure and effectiveness of PBOA

Strategic Initiatives

- 5.1** Maintain active and effective Board of Directors
 - Hold a minimum of 4 Board meetings per year
 - Maintain a minimum of 11 Board Members; consider succession planning and diversity
 - Engage Board regularly
 - Maintain and strengthen role of Executive Committee
- 5.2** Develop document of PBOA organization structure, identify gaps, ensure sustainability, execution
- 5.3** Improve IT infrastructure and communications, and manage robust website
- 5.4** Develop codes of conduct for Board membership, working group leadership, membership standards

Key Performance Measures

- Number of Active Board members and Board Meetings
- Revisit webpage for modifications and improvements
- Consider new and more effective communication tools
- Technology and organizational roadmaps presented to Board



PBOA Strategic Plan – 2020 thru 2024

Operating Plan by Year - 2020

Illustrative – separate spreadsheet to be maintained and memorialized

Strategic Goal 1: Establish PBOA as the public voice of the CMO/CDMO Sector

Initiative	Progress/Milestones
Increase visibility with US Federal Legislators thru obtaining audiences and participating in legislative meeting opportunities that can showcase the purpose of PBOA	Report 3 months on people/topics (+ conference calls) (written version for review by board)
Increase interactions with FDA and other key Ministries of Health	Report 3 months on agencies/topics (+ conference calls) (written version for review by board)
Seek opportunities for positive messaging about PBOA thru Industry Publications and other general interest and business media outlets. Seek opportunities to increase awareness of importance of CMO/CDMO Industry with Healthcare stakeholders and general public.	Report 6 months on publications, references
Identify and collectively prioritize members’ key issues and strategic goals	Seek feedback and re-prioritize goals, report to board

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Operating Plan by Year - 2020

Illustrative – separate spreadsheet to be maintained and memorialized

Strategic Goal 2: Advance policy and advocate on behalf of members with legislators and regulators

Initiative	Progress/Milestones
Establish and annually revise policy priorities document	Establish and compare over time
Assess legislative support in Washington – improve visibility to members	Report annually, board discussion
Be selective and pursue aggressively those policy areas of most importance to our members	Report quarterly
Recommend path forward for State issue identification and influence	Report regularly, prioritize states, assess investment
Identify members’ ex-US issues that leverage PBOA experience	Report regularly

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Operating Plan by Year - 2020

Illustrative – separate spreadsheet to be maintained and memorialized

Strategic Goal 3: Foster collaborative environment for developing policy recommendations via Working Groups, Conferences, and with other Associations and Stakeholders

Initiative	Progress/Milestones
Re-evaluate Working Group Structure with compliance code of conduct	Develop Code of Conduct for working groups
Continue to evolve the PBOA Conference concept. Increase attendance and relevance every year	Report on scheduling, attendance, revenues
Identify key issues for collaboration with other industry associations which overlap the goals of PBOA. Establish meaningful partnerships	Report regularly
Increase variety of opportunities for member companies to interact	Report on participation in Working Groups, conference, webinars
Assess CDMO crisis resilience and policy responses/recommendations	Conduct and report on survey of members re: COVID & other crises



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Operating Plan by Year - 2020

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Strategic Goal 4: Evolve and increase the reach and breadth of PBOA

Initiative	Progress/Milestones
Increase the number of Members of PBOA, including Affiliate Members	Report regularly
Consider all adjacent CMO Industries (i.e. Biotechnology Drug Substance, Cell and Gene Therapy, Specialty API) and tee up for a strategic discussion with Board and Membership	Report regularly on adjacent sectors
In annual consultation with Board, identify and hold meaningful meetings with Top 10 prospects	Report regularly, recruit board participation
Consider serving additional Geographies. Set Strategic direction in conjunction with Board and Membership	Report regularly



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Operating Plan by Year - 2020

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Strategic Goal 5: Evolve and improve the leadership, organizational structure and effectiveness of PBOA

Initiative	Progress/Milestones
Maintain active and effective Board of Directors	Review bylaws, report to board
Develop document of PBOA organization structure, identify gaps, ensure sustainability, execution	Assess/report needs analysis (annually/semiannually)
Improve IT infrastructure and communications, and manage robust website	Report regularly
Develop codes of conduct for Board membership, working group leadership, membership standards	Establish code, report on compliance, reassess