Executive Steering Committee Elections 2026

Nominee Name: Nayaz Ahmed
Current Position/Title: Founder, Principal
BioMaP-Consortium Member Organization: Indigo Life Sciences
ESC Seat Applying for: Regulatory, Quality, and Policy

Please describe how your background, training, and experience would support your ability to serve in a governance role on the Executive Steering Committee.

I bring more than 20 years of continuous, hands-on leadership in pharmaceutical and biopharmaceutical quality, regulatory affairs, and CMC development, spanning small molecules, peptides, biologics, plasmid-based vaccines (including commercial-scale COVID-19 manufacturing), viral vectors, and cell and gene therapies. This breadth across modalities and across the full development lifecycle, from early concept and process development through IND, BLA, NDA, and ANDA filings to commercial licensure, gives me a systems-level view of the regulatory and quality challenges that BioMaP-Consortium members face at every stage of biomanufacturing preparedness.

My governance readiness is grounded in direct accountability, not observation from the sidelines. As Head of Quality Control and Deputy Representative for the Quality Site Head at Thermo Fisher Scientific's Microbial Manufacturing Services, I built a QC center of excellence from the ground up for commercial-scale plasmid manufacturing supporting COVID-19 vaccines and supported the organization in obtaining a manufacturing license approval with zero 483 observations. At PrimaPharma, an FDA-registered, ISO-accredited CDMO, I served as Director of Analytical Services and Deputy Representative to Quality Management, where I helped resolve a warning letter and achieve a sustained record of zero 483 observations, while authoring CMC dossiers and directly liaising with FDA and EMA on outstanding compliance issues. These roles required exactly the skills a governance seat demands: representing an organization credibly to regulators and external stakeholders, building consensus across cross-functional and often competing priorities, and translating technical complexity into clear strategic recommendations for leadership.

My formal credentials reinforce this operational experience. I hold Regulatory Affairs Certification in both the US and EU, Certified Quality Auditor status from ASQ, and Six Sigma Green Belt certification, and I have served as an ad hoc grant reviewer for the NIH National Cancer Institute's peer review committee, an experience that required me to evaluate proposals objectively, deliberate collaboratively with fellow reviewers, and reach defensible group decisions, precisely the kind of committee-based judgment a governance

role requires. Since 2019, as Principal Consultant at Indigo Life Sciences, I have advised multiple biopharmaceutical organizations on CMC, quality, and regulatory strategy, giving me current, cross-company visibility into the preparedness gaps, workforce needs, and policy questions the BioMaP-Consortium is positioned to address.

Taken together, my technical depth across modalities, my direct experience representing organizations before regulatory authorities, my audit and quality-system leadership, and my track record of building and guiding teams toward compliant, high-quality outcomes equip me to serve effectively as a fiduciary and strategic voice on the Executive Steering Committee, advising the Consortium, its membership, the Consortium Management Firm, ATI, and U.S. Government partners with sound, experience-based judgment.

Please describe the relevant experience, expertise, and perspective you would bring to the ESC seat you selected.

I am applying for the Regulatory, Quality, and Policy seat because it sits squarely at the intersection of my career: identifying emerging regulatory and quality developments, translating them into actionable guidance, and connecting industry peers with the expertise needed to act on them. Over more than two decades, I have developed and executed phase-appropriate regulatory and CMC strategies across small molecules, peptides, biologics, plasmid vaccines, viral vectors, and cell and gene therapies, and I have authored and supported IND, NDA, BLA, ANDA, IMPD, and MAA submissions. This modality breadth mirrors the diversity of the BioMaP-Consortium membership and positions me to surface regulatory and policy developments that are relevant across, not just within, a single platform.

On the quality side, I have built and led Pharmaceutical Quality Systems and QMS frameworks from the ground up, most recently establishing the QC center of excellence for commercial-scale plasmid DNA manufacturing supporting COVID-19 vaccine production at Thermo Fisher Scientific, and earlier at PrimaPharma, where I managed QMS, CAPA, document control, and supplier qualification programs across small molecule and combination-product manufacturing. In both roles I worked directly with FDA and EMA to resolve CMC and compliance issues, including bringing organizations through 483 observations and a warning letter to sustained inspection readiness. That regulator-facing experience gives me a practical, current understanding of where agency expectations are tightening and where members most need clarity, exactly the kind of insight this seat is meant to channel into Consortium content, events, and newsletters.

My certifications, Regulatory Affairs Certification in the US and EU, Certified Quality Auditor, and Six Sigma Green Belt, reflect a sustained commitment to staying current on

evolving regulatory frameworks, including 21 CFR Parts 11, 210, 211, 600, 820, and 1271, EMA EudraLex Annex 11 and 15, and ICH Q1 through Q14. As a practicing auditor across first-party, second-party, product, process, and system audits, I bring an independent, detail-oriented perspective on where quality and compliance gaps typically emerge in biomanufacturing scale-up, which I believe is directly relevant to shaping the Consortium's regulatory-focused programming.

Since 2019, my consulting work through Indigo Life Sciences has kept me engaged across multiple organizations and modalities simultaneously, advising on CMC strategy, PQS implementation, and agency interactions in real time. This vantage point, combined with my technical publication and patent record, gives me both the breadth to represent the collective interests of BioMaP-Consortium members and the depth to serve as a credible resource connecting members with regulatory and quality expertise as biomanufacturing preparedness priorities continue to evolve.