

# Cooper BioPharma Consulting, LLC

*Strategic Scientific Leadership from Discovery to Approval*

## Capabilities Summary – Christopher B. Cooper, PhD

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### Overview

Cooper BioPharma Consulting provides senior-level scientific and strategic leadership to biotechnology, pharmaceutical, and global health organizations. Founded by **Christopher B. Cooper, PhD** – a veteran R&D executive with 35+ years across Pfizer, Bristol-Myers Squibb, and the Global Alliance for TB Drug Development – the firm delivers proven expertise in medicinal chemistry, preclinical development, CMC strategy, and regulatory submissions.

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### Core Competencies

#### 1. CMC / Drug Substance & Regulatory Strategy

- Route scouting, API process development, and scale-up strategy
- CDMO/CRO selection, management, and technical oversight
- FDA/EMA regulatory documentation expertise
- Author of **six IND (3.2.S)** and **one NDA/MAA (3.2.S)** submissions
- Experience supporting the **global approval and launch of pretomanid**

#### 2. Drug Discovery & Medicinal Chemistry Leadership

- Lead identification and lead optimization strategy
- Hit-to-lead and LO-to-candidate pathways
- Structure-based design and SAR development
- Direction and oversight of internal and external medicinal chemistry teams
- Expertise spanning infectious diseases, oncology, metabolic disease, cardiovascular disease, immunology, and CNS
- 18 patents and 58 peer-reviewed publications

#### 3. Preclinical & Translational Development

- Design, integration, and interpretation of PK/PD, DMPK, and *in vivo* model data
- IND-enabling study planning and risk mitigation
- Candidate nomination packages and stage-gated decision frameworks
- Scientific assessment of stalled or high-risk programs

#### 4. Portfolio & Program Leadership

- Evaluation and prioritization across discovery and preclinical pipelines
- Portfolio governance, milestone development, and scenario planning
- Independent due diligence for investors and strategic partnerships
- Leadership of multi-disciplinary teams (chemistry, biology, safety, CMC, clinical)

#### 5. Scientific Advisory & Executive Support

- Scientific Advisory Board service for academic, biotech, and global health programs
- Interim CSO/VP-level leadership for emerging companies
- Executive mentoring and team development
- Communication strategy for investors, executives, and regulatory submissions

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#### Key Achievements

- Led CMC and regulatory strategy for **pretomanid** → **FDA & EMA approval** (first-in-class antitubercular)
- Advanced **7+ clinical candidates** to Phase I/II/III trials
- Authored **6 IND (3.2.S)** and **1 NDA/MAA (3.2.S)** regulatory submissions
- Directed global chemistry/CMC networks: **70+ FTEs** across 21 CROs/CDMOs
- Managed 25-person medicinal chemistry team at Bristol-Myers Squibb
- Delivered **26+ programs** across oncology, infectious disease, metabolic disease, immunology, CNS
- 18 patents, 58 peer-reviewed publications
- 30+ invited international conference presentations

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#### Engagement Models

- **Consulting / Advisory** – hourly or daily
- **Project-based engagements** – fixed-fee assessments, IND packages, CMC reviews
- **Fractional leadership** – interim VP/CSO scientific leadership
- **Retainer arrangements** – ongoing strategic partnership with guaranteed availability

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#### Contact

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