

CURRICULUM VITAE

Dr. Somanath Basu

Senior Regulatory & Quality Expert

PROFILE SUMMARY

Senior regulatory and quality professional with over 34 years of experience in drug regulation, vaccine surveillance, clinical trial assessment, CMC dossier review, and national/international regulatory collaborations.

CORE COMPETENCIES

- Regulatory Dossier Assessment
 - Vaccine Surveillance
 - CMC Review
 - Pharmacovigilance (CIOMS/PSUR)
 - Drug Testing & Analysis
 - WHO NRA Collaboration
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PROFESSIONAL EXPERIENCE

- Scientist-F, QMS & Regulatory Services – AMTZ (2023 – Present)
 - Assistant Drugs Controller (India) – CDSCO (1995 – 2023)
 - Drug Analysis Assistant – CDL Calcutta (6+ years)
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EDUCATIONAL QUALIFICATIONS

- Master's in Biochemistry – University of Calcutta
 - Bachelor's in Chemistry – University of Calcutta
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