ARUN KUMAR SINGH

Global Regulatory Affairs Analyst and Consultant | Life Sciences Analytics | AI-Powered RA | Healthcare Science | CLM

USFDA | EU MDR/IVDR | MHRA | Health Canada | TGA | CDSCO | ISO 13485 | IEC 62304 | ISO 14971 | SaMD | eCTD | Drug Delivery | Medical Device

esqaks@gmail.com | +91 62902 40024 | Serampore, Kolkata, India | Open to Global Remote / Hybrid / Relocation

B.Sc. Biology (Physiology Major) | MBA-Symbiosis | LL.B.(BCI) | AI Certified (be10X 2025) | US Paralegal | Licensed Advocate | 25+ Yrs PQE

RA Website: just-yellow-y9ca39qgxh.edgeone.app | Resume: alslegalcare.edgeone.app | Legal: arunkumarsinghadv.netlify.app | Certs: drive.google.com/drive/folders/1k_nCG4b7ITyFE5Wi8e_ov9msy0ixnhTz

PROFESSIONAL SUMMARY

Cross-functional **Regulatory Affairs Analyst and Life Sciences Consultant** with a uniquely rare combination: pharmaceutical commercial leadership (8 years, Eastern India), NABH-accredited clinical hospital operations and medical device pre/post-sales management (8 years), multi-jurisdiction RA intelligence across USFDA, EU MDR/IVDR, MHRA, Health Canada, TGA, and CDSCO, AI-powered analytics capability, healthcare science knowledge spanning drug delivery systems, pharmacokinetics/pharmacodynamics, clinical evaluation, and 7-year in-house corporate legal practice. Expert in full eCTD lifecycle (IND, NDA, BLA, ANDA, DMF, EUA, 510(k), PMA, De Novo), SaMD regulatory frameworks (ISO 13485:2016, IEC 62304, ISO 14971:2019), CDSCO Form 40/10, CT-04, SUGAM portal, and CTRI Phase I-IV. Certified Medical Coder (ICD-10-CM, CPT, HCPCS, WHO-ICH, Modifiers). AI-powered researcher (Harvey AI, ChatGPT-4, Lexis Plus AI, Power BI) with 40% productivity gains. Launched first-in-India branded APIs including Clopidogrel, Parnaparin LMWH, Esmolol, and Carvedilol. Immediately available globally.

CAREER HIGHLIGHTS AND KEY PERFORMANCE INDICATORS

First-in-India	Launched branded APIs: Clopidogrel (P2Y12), Fenofibrate, Parnaparin LMWH (subcutaneous injectable), Esmolol HCl (IV beta-blocker), Carvedilol -- new therapeutic divisions at USV Ltd (1998-2003)
25% CAGR	Pharmaceutical territory revenue growth across 8 years -- Malda/North Bengal and Kolkata HQ (USV Ltd) and Eastern Region RM (Themis Medicare Ltd)
60 to 25 Days	Debtor ageing slashed from 60 days to 25 days (Themis Medicare) -- structured collection protocols, significantly improving regional cash flow and AR management
30% Growth	Institutional revenue growth as SBU Head -- B.M. Birla Heart Research Centre -- India's First NABH-Accredited Cardiac Hospital, Kolkata (2006-2014)
200+ KOLs	Key Opinion Leader network built -- consulting cardiologists, interventional cardiologists, cardiac surgeons -- across West Bengal and Eastern India
16-Member Team	Cross-functional team led as SBU Head -- pre/post-sales device collaborations: coronary stents BMS/DES, pacemakers, cath lab devices, cardiac valves
40% AI Efficiency	Research efficiency via Harvey AI, Lexis Plus AI, ChatGPT-4, Claude, Power BI -- AI prompt engineering and predictive algorithm creation -- daily practitioner
300+ Contracts	Commercial agreements drafted and negotiated -- pharma, medical device, real estate, FMCG, ITeS sectors -- INR 50+ crore value -- 85% litigation success rate
ICD-10-CM Cert.	Certified Medical Coder -- ICD-10-CM, CPT, HCPCS Level II, WHO-ICH / MedDRA, Modifiers, CMS-1500 filing, RCM/AR management (Udemy 2022)
100% Compliance	Zero show-cause notices, zero regulatory penalties across all organisations and all Indian and cross-border jurisdictions -- full statutory compliance record
6 Jurisdictions	Multi-jurisdiction RA knowledge: USFDA CDER/CDRH | EU MDR/IVDR | MHRA UK | Health Canada | TGA Australia | CDSCO India | ICH/IMDRF Global
Drug Delivery	Oral (P2Y12, PPAR-alpha, alpha/beta blocker) | Subcutaneous injectable LMWH | IV ultra-short beta-blocker -- full PK/PD applied physician education

HEALTHCARE SCIENCE | DRUG DELIVERY | PHARMACOLOGY | REGULATORY ANALYTICS | CLINICAL OPERATIONS

Healthcare Science and Drug Delivery Systems Knowledge (Hands-on Commercial and Clinical Experience):

DRUG DELIVERY SYSTEMS | PK/PD | PHARMACOLOGY | CLINICAL EVALUATION		
Oral Antiplatelet -- Clopidogrel P2Y12	Oral Lipid-Lowering -- Fenofibrate PPAR-alpha	Subcutaneous Injectable LMWH -- Parnaparin Na
IV Ultra-Short Beta-Blocker -- Esmolol HCl	Oral Alpha/Beta Blocker -- Carvedilol	Cardiology Tx: Anti-ischemic, Anti-hypertensive
ADME -- Absorption Distribution Metabolism Excretion	Bioavailability and Bioequivalence (BA/BE)	Half-life | Tmax | Cmax | AUC -- Physician Education
PK/PD Principles Applied in Scientific Detailing	CMC Module Drug Delivery Relevance	Cold Chain | Sterility Assurance (Parenterals)
Cardiac Stents BMS/DES -- Pre/Post-Sales	Pacemakers | Cardiac Cath Lab Devices	Cardiac Valves -- Mechanical and Bioprosthetic
NABH Standards -- Direct Hospital Experience	Clinical Establishments Act 2010	Patient Outcome Tracking | Adverse Event Awareness

Pharmaceutical and Life Sciences Regulatory Analytics (AI-Powered):

REGULATORY ANALYTICS | AI-POWERED RESEARCH | PREDICTIVE ALGORITHMS | PHARMACOVIGILANCE		
Predictive Algorithm Development	Regulatory Submission Success Probability	Drug Approval Timeline Forecasting Models
Adverse Event Signal Detection (AI)	Real-World Evidence (RWE) Analysis	PSUR / PBRER Intelligence Automation
AI-Assisted ICSR Processing	CIOMS WG XIV 2025 AI in PV Framework	FDA EDSTP -- Emerging Drug Safety Tech Programme
eCTD/CTD Gap Analysis -- AI-Assisted	Module Completeness Automated Checking	Labelling Intelligence Cross-Jurisdiction
Physician Rx Behaviour Analysis	Market Share and Territory Analytics	KOL Network Mapping and Acquisition Strategy
Power BI Regulatory Dashboards	Compliance KPI Visualisation	Post-Approval Lifecycle Management Reporting

AI Tools	Harvey AI | Lexis Plus AI | ChatGPT-4 | Claude | Microsoft Copilot | FDA Elsa (June 2025) | EMA Scientific Explorer | Casetext CoCounsel | n8n Automation | Power BI
Analytics Stack	Power BI -- Regulatory Dashboards | Excel Pivot/VLOOKUP/Power Query | SCC Online | Manupatra | FDA AccessData | EMA EUDAMED | CDSCO SUGAM | CTRI

GLOBAL REGULATORY AFFAIRS KNOWLEDGE -- MULTI-JURISDICTION -- ALL MAJOR AGENCIES AND STANDARDS

USFDA -- CDER | CDRH | ORA | Drugs | Biologics | Medical Devices | SaMD		
IND -- Investigational New Drug	NDA -- New Drug Application (21 CFR 314)	BLA -- Biologics License Application (21 CFR 601)
ANDA -- Abbreviated NDA (Generics)	DMF -- Drug Master File	EUA -- Emergency Use Authorization
510(k) Premarket Notification	PMA -- Premarket Approval	De Novo -- Novel Device Classification
eCTD -- Electronic Common Technical Document	AND | NID Filing | COSM | ESG Filing	CDRH -- Medical Device Submissions
SaMD -- Software as a Medical Device	QMSR -- 21 CFR Part 820 (Feb 2026)	FDA Class I | II | III Medical Devices
IVD -- In Vitro Diagnostics	Design Controls -- 21 CFR 820.30	FDA Elsa AI Tool (June 2025) -- Agency-Wide GenAI

EU | MHRA UK | HEALTH CANADA | TGA AUSTRALIA | CDSCO INDIA

EU MDR 2017/745 -- Class I, IIa, IIb, III	EU IVDR 2017/746 -- IVD Classification	CE Marking -- Notified Body Process
MHRA MIA | MS | MIA(IMP) | WDA(H)	EDQM CEP -- Certificate of Suitability	DPO Register -- Data Protection Officer
Health Canada eCTD | NDS | ANDS | CTA	Medical Devices Class II | III | IV	TGA Category 1 | 2 | 3 | OTC | SAR
CDSCO Form 40 and 10 | CT-04	NDA CT-21/CT-23 | SUGAM Portal	Medical Device Rules 2017
CTRI Phase I-IV Registration	Pharmacovigilance PvPI | PMS India	Schedule Y | GCP Guidelines India

QMS | ISO 13485 | IEC 62304 | ISO 14971 | ICH | GxP | MEDICAL CODING | LEGAL		
ISO 13485:2016 -- QMS Medical Devices	IEC 62304 -- Software Lifecycle Processes	ISO 14971:2019 -- Risk Management
IEC 82304-1 -- Health Software Safety	IEC 62366-1 -- Usability Engineering	ISO 27001 -- Information Security
ICH E6 R2 | Q8 | Q9 | Q10 | M4 CTD	21 CFR Part 11 -- Electronic Records	GMP | GLP | GCP | GDP | CAPA
ICD-10-CM | CPT | HCPCS | MedDRA	CMS-1500 | RCM | AR Management | HIPAA 837P	WHO-ICH Classification | Modifiers
CLM -- Icertis | Sirion | Ironclad | Agiloft	CTAs | CRO/CMO | PV Agreements | CLM Full Lifecycle	DPDP Act 2023 | Companies Act 2013 | FEMA | PMLA

PROFESSIONAL EXPERIENCE -- PHARMACEUTICAL | CLINICAL | MEDICAL DEVICE | LEGAL

Senior Manager -- Growth, Development and Compliance | SBU Head

April 2006 -- March 2014

B.M. Birla Heart Research Centre | Kolkata

India's First NABH-Accredited Cardiac Hospital | 500+ Employees | 16-Member Team

- **Revenue Growth and Strategy:** Designed and implemented comprehensive revenue growth strategies achieving 30% institutional revenue growth. Built referral network of 200+ consulting cardiologists and interventional cardiologists across West Bengal and Eastern India. Collaborated with departments across cardiology, nursing, finance, and administration for seamless patient experience driving positive word-of-mouth and measurable revenue contribution.
- **Team Leadership (16 members):** Recruited, hired, and coordinated training of all clinical and non-clinical staff across business development, referral management, brand management, CME organisation, outreach, and content development. Managed staff by assigning and delegating tasks, conducting quarterly and annual performance reviews with structured constructive feedback to help each professional meet their goals.
- **Medical Device Collaboration (Pre/Post-Sales):** Led full pre-sales to post-sales collaboration with medical device companies across coronary stents (BMS/DES), cardiac pacemakers, cath lab devices (guiding catheters, balloon catheters, guide wires), and cardiac valves (mechanical and bioprosthetic) -- gaining practical understanding of Medical Device regulatory lifecycle, post-market surveillance, and vigilance requirements applicable to 510(k)/PMA/MDR 2017 regulatory strategy.
- **CME, Outreach and Vendor Management:** Organised CME programmes, cardiac screening camps, and corporate health partnerships with medical device companies. Managed vendor relationships -- medical equipment suppliers, device companies, service providers -- negotiating contracts, monitoring SLAs, and ensuring value delivery aligned to clinical quality standards.
- **Healthcare Regulatory Compliance:** Managed NABH re-accreditation cycles, Clinical Establishments Act 2010, Drugs and Cosmetics Act 1940, Medical Devices Rules, bio-medical waste regulations, EPF, ESIC, POSH Act for 500+ employee facility. 100% compliance record -- zero penalties across all healthcare regulatory audits.
- **EMR and Patient Satisfaction Analytics:** Worked with data team to input and maintain patient information in electronic medical records system. Collected and analysed patient satisfaction feedback -- implemented service adjustments achieving measurable improvements in satisfaction scores and referral outcomes.

Regional Manager -- Pharmaceutical Sales | Team Leader

April 2003 -- March 2006

Themis Medicare Limited | Eastern India

Cardiology | Diabetology | GM | Team of 12-14 | Burdwan then Kolkata HQ

- Led team of 12 (Burdwan) scaled to 14 (Kolkata -- new Cardiac Division launch) achieving **25% revenue growth and 10% Rx growth**. Reduced debtor ageing from **60 to 25 days** through structured collection protocols and distributor relationship management, significantly improving cash flow.
- Conducted in-depth doctor psychology analysis, Rx behaviour surveys, and market research to design and launch new Cardiac Division. Ensured Drugs Act 1940, GMP, and CDSCO regulatory compliance across all territory operations.

Territory Sales Manager -- Pharmaceuticals | First-in-India API Launches

April 1998 -- March 2003

USV Limited | Malda / North Bengal and Kolkata HQ

Cardiology | Diabetology | General Medicine | Eastern India Territory

- Launched **first-in-India branded APIs**: Clopidogrel (P2Y12 inhibitor, oral antiplatelet), Fenofibrate (PPAR-alpha agonist, lipid-lowering), LMWHs -- Parnaparin Sodium (subcutaneous injectable anticoagulant), Esmolol HCl (IV ultra-short beta-1 blocker), Carvedilol (oral alpha/beta blocker) -- requiring deep drug mechanism, PK/PD principles, regulatory approved indications, labelling, and physician education knowledge. Achieved consistent **25% CAGR** through structured territory management and scientific education programmes.

Senior Legal Counsel and Corporate Compliance Manager

January 2018 -- Present

Zeal Group of Companies | PAN India

Manufacturing | FMCG | Real Estate | ITeS | Import-Export -- 7 Industry Sectors

- Managing all day-to-day legal affairs and statutory compliance across seven industry verticals -- developing deep expertise in regulatory document management, compliance frameworks, government submissions, and cross-border regulatory requirements directly applicable to global RA roles. **300+ commercial agreements drafted and negotiated** (INR 50+ crore value) including CTAs, CRO/CMO agreements, PV agreements, technology transfer agreements, distribution agreements, and CLM platform application.
- AI-powered legal and regulatory research practitioner delivering 40% research efficiency via Harvey AI, Lexis Plus AI, ChatGPT-4, and Claude. Created predictive outcome algorithms using prompt engineering applicable to RA regulatory intelligence workflows. 85% litigation success rate across 40+ civil, labour, consumer, NCLT, DRT, and High Court proceedings.

EDUCATION AND PROFESSIONAL CREDENTIALS

ACADEMIC QUALIFICATIONS		
B.Sc. Biology -- Physiology Major	Calcutta University -- 1993	Pharmacology | Physiology | Biochemistry | Bio-sciences
MBA -- Marketing and Business Dev.	Symbiosis International University -- 2009	Business strategy | Analytics | Commercial operations
LL.B. (BCI Approved)	Kalinga University -- 2017	Regulatory law | Contracts | Compliance frameworks
Master Diploma -- Digital Marketing	Kallada Academy -- 2021	Life sciences digital outreach | Content strategy
Adv. Diploma -- Computer Science	Aptech -- 1996	IT foundation | Programming | Systems | Databases
LL.M. Coursework -- Pursuing	Kalinga University -- Ongoing	Advanced regulatory and compliance law

CERTIFICATIONS -- Portfolio: drive.google.com/drive/folders/1k_nCG4b7ITyFE5Wi8e_ov9msy0ixnhTz		
Medical Coding ICD-10-CM/CPT/HCPCS/WHO-ICH/Modifiers (Udemy 2022)	AI Tools and Legal Practice -- be10X Workshop (Dec 2025)	US Paralegal and Contract Drafting -- Innovation School Canada
Contract Law and Drafting -- Khaitan and Co.	GDPR and DPDP Act 2023 -- Data Privacy Compliance	Arbitration and Conciliation Act -- Growth School
IPR and Trademark -- Fox Mandal / Law School	Labour Codes and Employment -- LawSikho	RERA and Transfer of Property -- Practical Training
Bar Council CLE -- BNS/BNSS/BSA 2023 | IBC | DPDP Act	Medical Regulatory Documentation -- Healthcare Compliance	IRS Publications P17 | P17A | P54 -- Applied Practice

CONTRACT LIFECYCLE MANAGEMENT (CLM) -- PHARMA AND LIFE SCIENCES PLATFORMS

Full CLM Lifecycle	Initiation and Request | Clause Library Authoring | AI Risk Scoring | Redlining and Version Control | Multi-party Review Workflows | GxP e-Signature (21 CFR Part 11) | Obligation Tracking | Renewal Alerts | Portfolio Analytics

Pharma Contract Types	Clinical Trial Agreements (CTAs) | Site CDAs | CRO/CMO Agreements | Pharmacovigilance Agreements | Technology Transfer Agreements | API Supply Agreements | Distribution Agreements | License Agreements (Royalty Structures) | Co-Promotion Agreements
CLM Platforms	Icertis Contract Intelligence (5 of top 7 pharma companies | Gartner Leader) | Sirion (AI-Native Agentic CLM) | Ironclad CLM (Gartner Leader | 1B+ contracts) | Agiloft (No-code | GxP) | DocuSign CLM + Evisort AI | Conga CLM (Salesforce-native) | ContractPodAi / Leah (Agentic) | Spellbook / Kira (In-Word AI)

TECHNOLOGY | AI PROFICIENCY | REGULATORY DIGITAL TOOLS | MEDICAL CODING

AI RA Research	Harvey AI | Lexis Plus AI | Casetext CoCounsel | ChatGPT-4 | Claude | Microsoft Copilot | FDA Elsa (2025) | EMA Scientific Explorer | Spellbook
Regulatory DB	FDA.gov CDER/CDRH | EMA EUDAMED | MHRA DORS | Health Canada DPD | TGA TBS | CDSCO SUGAM | CTRI | ICH | SCC Online | Manupatra | Indian Kanoon
RA/QMS Tools	eCTD Publishing (conceptual) | Veeva Vault (awareness) | Document Control | CAPA Management | eQMS Frameworks | ISO 13485 Audit Trails
Analytics	Power BI Regulatory Dashboards | Excel Pivot/VLOOKUP/Power Query | Compliance KPI Tracking | Market Intelligence Reports | Predictive Outcome Models | AI Signal Detection
Medical Coding	ICD-10-CM | CPT | HCPCS Level II | MedDRA/WHO-ICH | Modifiers | CMS-1500 Abstraction and Filing | RCM and AR Management | HIPAA 837P | Denial Management
MS Office	Advanced Word (tracked changes, mail merge) | Excel (Pivot tables, VLOOKUP, Power Query) | Outlook | PowerPoint | Teams | SharePoint | DocuSign | n8n Automation

COMPREHENSIVE REGULATORY KNOWLEDGE -- ALL MAJOR STATUTES | JURISDICTIONS | COMPLIANCE FRAMEWORKS

USFDA CDER/CDRH/ORA | eCTD | IND | NDA | BLA | ANDA | DMF | EUA | AND | NID | COSM | 510(k) | PMA | De Novo | Q-Sub | SaMD | QMSR 21 CFR 820 | Design Controls 21 CFR 820.30 | 21 CFR Part 11 | EU MDR 2017/745 | EU IVDR 2017/746 | CE Marking | EUDAMED | CER | PMCF | EMA MAA | MHRA MIA | MS | MIA(IMP) | WDA(H) | EDQM CEP | DPO Register | Health Canada NDS | ANDS | CTA | NOC | TGA Cat 1/2/3 | OTC | SAR | ARTG | CDSCO Form 40/10 | CT-04 | NDA CT-21/CT-23 | SUGAM Portal | Medical Device Rules 2017 | CTRI Phase I-IV | Schedule Y | PvPI | PMS | ISO 13485:2016 | IEC 62304 | ISO 14971:2019 | IEC 82304-1 | IEC 62366-1 | ISO 27001 | ICH E6 R2 | Q8 | Q9 | Q10 | M4 CTD | M7 | GCP | GMP | GLP | GDP | CAPA | SOUP | Software Class A/B/C | ICD-10-CM | CPT | HCPCS | MedDRA | CMS-1500 | RCM | HIPAA 837P | EU AI Act 2024 | FDA AI/ML Guidance 2025 | FDA Elsa AI Tool | EMA Scientific Explorer | Companies Act 2013 | IBC 2016 | PMLA 2002 | FEMA 1999 | SEBI | DPDP Act 2023 | Consumer Protection Act 2019 | NABH Standards

RA Website: just-yellow-y9ca39qgxh.edgeone.app | Resume Dashboard: alslegalcare.edgeone.app | Legal Site: arunkumarsinghadv.netlify.app | Certifications: drive.google.com/drive/folders/1k_nCG4b7ITyFE5Wi8e_ov9msy0ixnhTz | LinkedIn: linkedin.com/in/arun-kumar-singh-esq | esqaks@gmail.com | +91 62902 40024 | References available on request | Immediately available