



AARAV SHAH

Regulatory Affairs Specialist

dossier coordination, document control, submission planning

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FICTIONAL SAMPLE - all employers, qualifications and outcomes are illustrative and unverified.

EXECUTIVE SUMMARY

Regulatory Affairs Specialist with an illustrative 12-year career in pharmaceutical services, clinical research and scientific documentation. Combines dossier coordination, document control, submission planning with disciplined documentation, practical coordination and clear communication. The sample career progresses from focused execution to independent workstream ownership, with responsibilities and boundaries described for each appointment.

Selected work includes dossier readiness programme, regulatory change register and authority query coordination. These examples explain the original problem, individual contribution, deliverables, review approach and remaining limitations rather than relying on unsupported headline claims.

Prepared for experienced regulatory affairs specialist opportunities requiring dependable delivery, thoughtful professional judgement and collaboration. The qualification narrative includes M.Sc in Regulatory Affairs. Every named organisation and outcome in this record is fictional; professional eligibility is not independently established.

AT A GLANCE

12 years ILLUSTRATIVE CAREER	4 CAREER APPOINTMENTS	3 WORK EXAMPLES	2 EDUCATION RECORDS
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CORE COMPETENCIES

- dossier coordination / document control
- submission planning / technical writing
- change tracking / cross-functional review
- requirements mapping / query management

PROFESSIONAL MISSION

Turn a clear brief into dependable pharmaceutical services, clinical research and scientific documentation work: understand the context, apply dossier coordination and document control, record the evidence and explain the limitations before handover.

Career family: Pharmacy, Biotechnology & Life Sciences | Snapshot: 2026-09-22

PROFESSIONAL EXPERIENCE / RECENT

Regulatory Affairs Specialist

Meridian Life Sciences (fictional)

Jul 2023 - Present | Bengaluru, India

Independent ownership of scoped regulatory affairs specialist work, coordinating contributors and making review requirements explicit. Includes the first two selected work examples.

- Mapped documents and coordinated review checkpoints.
- Built dated source references and impact reviews.
- Led brief clarification and prioritised work using dossier coordination, document control and submission planning. Raised unresolved constraints before committing to the next stage.
- Coordinated peer reviews and handover preparation; used a controlled procedure or study document to distinguish completed work, assumptions and follow-up needs.
- Supported colleagues with practical examples of technical writing and maintained a concise learning record after important assignments.

Illustrative career responsibilities. Employer confirmation and underlying work records are not supplied.

Senior Regulatory Affairs Specialist

Northline Life Sciences (fictional)

Jul 2019 - Jun 2023 | Bengaluru, India

Owned defined assignments and supported cross-functional coordination. Developed deeper practice in submission planning and technical writing.

- Structured question tracking and reviewed response packages.
- Translated incoming requirements into a sequenced plan and aligned responsibilities with the project or service owner.
- Applied change tracking and cross-functional review to resolve delivery questions while maintaining source and decision notes.
- Introduced reusable working documents and reviewed exceptions with the responsible specialist rather than silently changing scope.
- Prepared a scientific or quality summary so the next team could understand the work and remaining questions.

Illustrative career responsibilities. Employer confirmation and underlying work records are not supplied.

PROFESSIONAL WORKING PRINCIPLES

- Maintain controlled records, traceability and defined review responsibilities.
- Use appropriate supervision and distinguish exploratory findings from validated conclusions.
- Protect participant information and never treat fictional data as regulated evidence.

PROFESSIONAL EXPERIENCE / EARLIER

Regulatory Affairs Specialist

Cedarbridge Life Sciences (fictional)

Jul 2016 - Jun 2019 | Bengaluru, India

Progressed from supported tasks to independently managed assignments, with review available for unfamiliar or higher-risk decisions.

- Handled recurring work involving dossier coordination and document control using a documented preparation and review process.
- Supported regulatory change register by organising inputs, maintaining issue notes and incorporating reviewer feedback.
- Coordinated colleagues and internal stakeholders using concise status updates, clear questions and agreed next steps.
- Improved record consistency through requirements mapping and documented handover expectations.

Illustrative career responsibilities. Employer confirmation and underlying work records are not supplied.

Regulatory Affairs Specialist

Cedarbridge Life Sciences (fictional)

Jul 2014 - Jun 2016 | Bengaluru, India

Built practical foundations through supervised assignments, routine documentation and feedback from experienced colleagues.

- Assisted with dossier coordination and submission planning within an agreed scope and escalated unfamiliar work.
- Prepared inputs and checked completeness before passing work to the responsible reviewer.
- Maintained task records and learned to communicate assumptions, constraints and observed problems clearly.
- Applied review feedback to subsequent assignments and developed a dependable working routine.

Illustrative career responsibilities. Employer confirmation and underlying work records are not supplied.

SELECTED CONTRIBUTIONS

Dossier readiness programme. Mapped documents and coordinated review checkpoints. The achievement is the described workstream contribution; independent outcome evidence is not supplied.

Regulatory change register. Built dated source references and impact reviews. The achievement is the described workstream contribution; independent outcome evidence is not supplied.

Authority query coordination. Structured question tracking and reviewed response packages. The achievement is the described workstream contribution; independent outcome evidence is not supplied.

SELECTED WORK / 01

Dossier readiness programme

P1 | Jan 2024 - Jun 2024 | FICTIONAL WORK EXAMPLE

Context. Fictional internal work programme in pharmaceutical services, clinical research and scientific documentation; not a real client case study.

Problem. Submission sections had inconsistent ownership and status.

Objective. Create a workable response to this issue through dossier coordination, explicit review criteria and practical documentation. Agree the boundaries before execution and retain unresolved points for follow-up.

Contribution and ownership. Regulatory Affairs Specialist; owned the stated workstream, not the full organisation or every collaborator contribution.

- Mapped documents and coordinated review checkpoints.
- Prepared the scope with the commissioning team, identified unresolved inputs and used dossier coordination to turn the brief into a sequenced work package.
- Applied document control and submission planning while coordinating reviews with the designated owner. Kept decision notes so collaborators could separate facts, assumptions and changes.
- Assembled the handover material, explained open limitations and agreed which items needed further review rather than presenting them as completed.

Methods. dossier coordination / document control / submission planning / technical writing

Deliverables. Dossier readiness programme - scoped brief; Dossier readiness programme - reviewed working package; Dossier readiness programme - handover and learning summary

Review. Reviewed the scoped output against the agreed brief, recorded exceptions and checked that key conclusions could be traced to observations. The review package calls for a controlled procedure or study document and a named human reviewer.

Illustrative outcome: the team adopted a repeatable approach for dossier readiness programme, with clearer ownership and reviewable records. This is a fictional qualitative result; no real performance measurement or external acceptance evidence is supplied.

Suggested evidence (not supplied): controlled procedure or study document; traceability and review log; scientific or quality summary.

SPECIALIST PRACTICE

Regulated evidence

The sample focuses on dossier coordination, document control, submission planning. Approvals, supervision and specialist input are identified in each work package; work outside this scope is referred to the designated responsible person.

Peer learning and practical guidance. Created short examples on dossier coordination and technical writing for colleagues. Separated personal preferences from agreed team procedures and recorded useful questions.

Review and handover discipline. Facilitated practical reviews of regulatory change register, ensuring that unresolved issues retained a named owner rather than disappearing from final presentations.

No pharmacy registration, clinical trial approval, product authorisation or validated laboratory result is supplied.

SELECTED WORK / 02 AND 03

Regulatory change register

P2 | Jan 2025 - Jun 2025 | Meridian Life Sciences (fictional)

Problem. Teams could not connect updates to affected records.

Objective. Create a workable response to this issue through document control, explicit review criteria and practical documentation. Agree the boundaries before execution and retain unresolved points for follow-up.

Ownership. Regulatory Affairs Specialist; owned the stated workstream, not the full organisation or every collaborator contribution.

- Built dated source references and impact reviews.
- Prepared the scope with the commissioning team, identified unresolved inputs and used submission planning to turn the brief into a sequenced work package.
- Applied technical writing and change tracking while coordinating reviews with the designated owner. Kept decision notes so collaborators could separate facts, assumptions and changes.
- Assembled the handover material, explained open limitations and agreed which items needed further review rather than presenting them as completed.

Methods. document control / submission planning / technical writing / change tracking

Delivered. Regulatory change register - scoped brief; Regulatory change register - reviewed working package; Regulatory change register - handover and learning summary

Illustrative outcome: the team adopted a repeatable approach for regulatory change register, with clearer ownership and reviewable records. This is a fictional qualitative result; no real performance measurement or external acceptance evidence is supplied.

Suggested evidence (not supplied): controlled procedure or study document; traceability and review log; scientific or quality summary.

Authority query coordination

P3 | Jan 2020 - Jun 2020 | Northline Life Sciences (fictional)

Problem. Responses arrived without a coherent evidence trail.

Objective. Create a workable response to this issue through submission planning, explicit review criteria and practical documentation. Agree the boundaries before execution and retain unresolved points for follow-up.

Ownership. Regulatory Affairs Specialist; owned the stated workstream, not the full organisation or every collaborator contribution.

- Structured question tracking and reviewed response packages.
- Prepared the scope with the commissioning team, identified unresolved inputs and used change tracking to turn the brief into a sequenced work package.
- Applied cross-functional review and requirements mapping while coordinating reviews with the designated owner. Kept decision notes so collaborators could separate facts, assumptions and changes.
- Assembled the handover material, explained open limitations and agreed which items needed further review rather than presenting them as completed.

Methods. submission planning / technical writing / change tracking / cross-functional review

Delivered. Authority query coordination - scoped brief; Authority query coordination - reviewed working package; Authority query coordination - handover and learning summary

Illustrative outcome: the team adopted a repeatable approach for authority query coordination, with clearer ownership and reviewable records. This is a fictional qualitative result; no real performance measurement or external acceptance evidence is supplied.

Suggested evidence (not supplied): controlled procedure or study document; traceability and review log; scientific or quality summary.

EDUCATION AND SPECIALIST LEARNING

M.Sc in Regulatory Affairs

Asterbridge Institute of Professional Studies (fictional institution)
Jul 2012 - May 2014 | completed - fictional record
Focus: dossier coordination, document control, technical writing. Specialist study on dossier readiness programme; an illustrative learning project, not a published result.

B.Pharm

Cedarhaven College of Applied Studies (fictional institution)
Jul 2008 - May 2012 | completed - fictional record
Focus: submission planning, change tracking, cross-functional review. Applied coursework in dossier coordination, documentation and reviewed practical assignments.

CONTINUING PROFESSIONAL DEVELOPMENT

Scientific documentation workshop (2023). Dossier coordination and technical writing in the context of regulatory affairs specialist work. Used reflective exercises and a bounded practice example related to dossier readiness programme.

Research data integrity lab (2024). Document control and change tracking in the context of regulatory affairs specialist work. Used reflective exercises and a bounded practice example related to regulatory change register.

Quality review and traceability seminar (2025). Submission planning and cross-functional review in the context of regulatory affairs specialist work. Used reflective exercises and a bounded practice example related to authority query coordination.

Provider for these illustrative learning records: Meridian Professional Learning Studio (fictional). Not a licence or certification.

LANGUAGES AND WORKING PREFERENCES

English and Hindi - professional working proficiency in this fictional record.

Work arrangement: onsite or hybrid by role requirements. Relocation: open to discussion - sample preference.

Availability: not confirmed; discuss before an interview.

CREDENTIAL AND EVIDENCE STATUS

No pharmacy registration, clinical trial approval, product authorisation or validated laboratory result is supplied.

Synthetic qualification and institution names illustrate profile fields only; they are not a validated qualification route or recognised accreditation claim.

No real referee, endorsement, award, publication, membership or licence is supplied.

Use for templates, product demonstrations and test data only. Replace fictional claims and remove the demo label only after approval of real candidate information.

Contact placeholder: aarav.shah@example.com. No phone, live profile URL or verified reference is supplied.

Complete machine-readable data: profile.json. Interactive companion: portfolio.html. Reference CV used for structure only; this is not Ajay Prajapat's biography.