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Navigating the Product Development Process

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RA Product Development Role

Teams need an RA professional to:

1. Develop an effective regulatory strategy and plan that meets project objectives
2. Provide input for design decisions initially and throughout the project
3. Identify applicable regulations to be addressed in product requirements
4. Provide input and guidance to risk & hazard analysis



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RA Product Development Role

Teams need an RA professional to:

5. Clearly communicate and track team deliverables for regulatory submissions
6. Work effectively with team members to prepare, review, and finalize materials for national & international submissions
7. Achieve timely regulatory approvals & clearances

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Team Membership Responsibilities

1. Establish solutions-oriented relationship with team
2. Be active in helping teams think through and solve problems
3. Represent RA management to team and vice versa

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Team Membership Responsibilities

4. Ensure subject matter experts are consulted and listened to carefully
5. Ensure Regulatory Plan is updated and current at the end of each phase
6. Identify ways to simplify registrations of next-generation products

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Regulatory Strategy Development

1. Spend sufficient time with team members to understand product design goals & essential features
2. Understand key product requirements & claims for each target market
3. Learn differences relative to existing product line & competitors' products

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Regulatory Strategy Development

4. Prepare draft Regulatory Strategy & review with key stakeholders
5. Present to team and check for essential understandings
6. Work with team members to ensure project plans are consistent with Regulatory Strategy

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Design & Development Input

1. Participate in team meetings to understand ongoing design issues and project constraints
2. Provide regulatory guidance to help assess design tradeoffs
3. Ensure claims are finalized and implications clear

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Design & Development Input

4. Learn product features / functionality
5. Help identify risks & hazards related to safe and effective use of the product
6. Inform team of new regulations & applicable guidance documents
7. Provide input to help plan transition to next generation products

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Project Schedule Planning

1. Identify key tasks, timing and interdependencies for upcoming submissions
2. Ensure tasks & dependencies are accurately shown in project schedule
3. Follow up with team members to review progress on related tasks

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Translation of Regulations

1. Summarize applicable regulations and guidance documents
2. Help teams interpret regulations & guidance documents appropriately
3. Provide regulatory insight to help team members establish performance requirements

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Translation of Regulations

4. Review test plans with team members to ensure regulations are addressed
5. Work with teams to ensure project documentation is suitable for regulatory submissions
6. Confirm schedule with team members for providing test results

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Labeling Guidance

1. Provide Regulatory requirements for product labeling
2. Communicate to content developers
3. Review labeling to ensure requirements are implemented appropriately
4. Provide guidance as needed and as new information is available

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Managing Team Deliverables

1. Prepare detailed list of Deliverables needed for Regulatory Submissions
 - Content outline
 - Clear description of each item needed
 - Information required for each item
 - Desired Format (table, graph, etc.)
 - Owner (primary + supporting)
 - Due date (drafts, reviews, final)

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Managing Team Deliverables

2. Clarify references required
3. Help Project Management create tracking chart & update regularly
4. Set intermediate delivery dates
 - Draft some sections early in project
5. Follow up individually with each owner

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Managing Team Deliverables

6. Report progress at team meetings – highlight critical & risk areas
7. Ask for help to track and obtain deliverables from team members
8. Conduct team working sessions
9. Take responsibility to ensure timely completion

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Reaching out to Global Teams

1. Set up conference calls early in project to plan & implement tasks
2. Form sub-teams with key contributors
3. Use web or video conferencing to maximize effectiveness
4. Initiate trips to work in person with remote team members

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Reaching out to Global Teams

5. Plan sessions across time zones when attendees will be on-line and alert
6. Be organized prior to conference calls to maximize effectiveness
7. Summarize decisions & action items
8. Stay in contact with people through emails & phone calls

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Summary of Key Points

1. Provide Development Teams with:
 - Regulatory Strategy & Plan
 - Input to design & development decisions
 - Translation of regulatory requirements
 - Input to risk & hazard analysis
 - Guidance for team member deliverables
 - Effective working sessions
 - Successful regulatory submissions

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Summary of Key Points

2. Offer solutions-oriented approach
3. Represent RA management to team
4. Work closely with team members to achieve high quality deliverables, on time
5. Use best practices in global communications
6. Proactively plan for future products and submissions

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