



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Conversations That Matter: Health Authority Interactions

Considerations for Helpful HA Interactions



Regulatory Capabilities

Characteristic/Capability	Why It's Important
Strong Communication Skills	Facilitates clear, effective interactions and avoids misunderstandings.
Regulatory Expertise	Ensures compliance with complex, evolving regulations.
Strategic Thinking	Aligns regulatory processes with company goals, anticipating issues.
Relationship-Building	Builds trust with health authorities, easing collaboration.
Attention to Detail	Prevents errors that could delay approvals or cause rejections.
Knowledge of Processes	Ensures timely, accurate submissions and adherence to procedures.
Critical Thinking	Enables effective risk assessment and problem-solving.
Negotiation Skills	Advocates for the company while ensuring regulatory compliance.
Organizational Skills	Manages multiple projects and deadlines efficiently.
Integrity and Ethics	Maintains credibility and ensures compliance with regulations.
Emotional Intelligence	Helps navigate stress and complex relationships with health authorities.

Good Interaction Practices

Best Practices for Effective Interaction



Interaction

- Building Relationships
- Clear, Transparent Communication
- Responsiveness
- Proactive Problem-solving
- Adherence to Compliance

Communication Techniques



- Active Listening
- Asking Questions / Seek Clarity
- Transparency / Accuracy
- Documentation

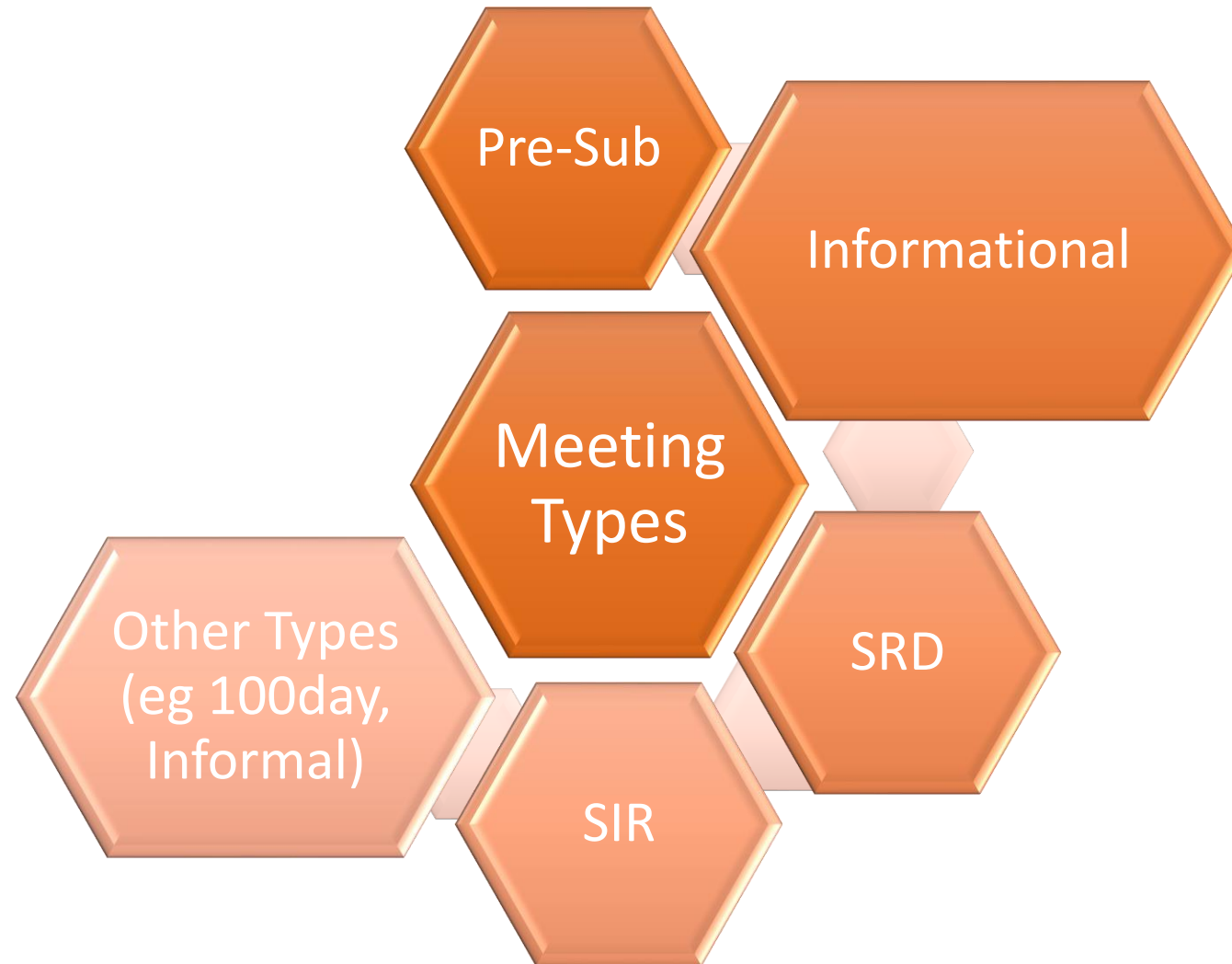
Common Challenges to Avoid



- Misunderstanding of Objectives
- Complexity of Regulations
- Communication Barriers
- Limited Resources

Regulatory Framework: FDA Q-Sub Model

- Offers early interaction
- Improve the quality of submissions
- Shorten review times
- Facilitate development process for new devices
- Voluntary
- Formal and Informal Feedback Options



Thank you!