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Thank you to everyone who joined RQA's Quality Conversation featuring our FDAQRC experts.

Within this clickable PDF, please find helpful links and sources below. If you have any questions about the presentation or would like to learn how FDAQRC can support your organization's inspection readiness needs, we'd be happy to connect.

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Chris Rush
FDAQRC President
chris@fdaqrc.com

Randall Morris
Inspection Readiness Advisor / Senior GCP Auditor
r.morris@fdaqrc.com

General Resources

- **Investigator Operations Manual 2025 (IMO)**
  www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual
- **Regulatory Procedures Manual 2025 (RPM):**
  www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual
- **Federal Food, Drug & Cosmetic Act (FD&C):**
  www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act
- **RRA Staff Manual Guide (RRA):**
  www.fda.gov/media/186992/download
- **FDA Staff Manual Guides (SMGs):**
  www.fda.gov/about-fda/reports-manuals-forms/staff-manual-guides
- **FDA Compliance Program Guidance Manual (CPGM):**
  www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/compliance-program-manual
- **FDA Guidance Documents:**
  www.fda.gov/regulatory-information/search-fda-guidance-documents
- **FDA Quality & Regulatory Consultants**
  www.fdaqrc.com | Contact form: www.fdaqrc.com/contact

Helpful Sources:

- IOM 5.14 – BIMO establishment types
- FD&C Act, Section 704 [21 U.S.C. 374] – Basic authority for inspections
- FD&C Act, Section 704(a)(5) [21 U.S.C. 374(a)(5)] – Authority for BIMO inspections
- IOM 5.14.4 – Postmarketing Adverse Event Reporting Inspections (21 CFR 310.305, 314.80, 314.98, 314.540, 329.100; 21 CFR 600.80)
- IOM 5.14.5 – REMS Reporting Inspections (FD&C Act §505-1)
- SMG 6001.1 – Remote Regulatory Assessments (RRAs)
- IOM 5.2.7 – Pre-Announcement for inspections
- IOM 5.10.1.1.1 – Basic Premises
- IOM 5.5.12.3 – Reportable Observations
- RPM 3.5.4 – Disqualification of Clinical Investigators
- CPGM 7348.811 – Bioresearch Monitoring: Clinical Investigators and Sponsor Investigators

Links

- **FDA Launches Agency Wide AI Tool: Elsa**
  www.clinicalleader.com/doc/cs-for-responding-to-fda-s-strategies-for-effective-compliance-and-resolution-0001
- **5 Cs – Clear, Concise, Compelling, Complete, Compliant (for FDA 483 responses)**
  www.clinicalleader.com/doc/cs-for-responding-to-fda-s-strategies-for-effective-compliance-and-resolution-0001