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3D Printing in Pharma: Regulatory and Compliance Expectations in the Digital Age

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NEXT-GENERATION DELIVERY INNOVATIONS

Overview

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1. **FDA support programs for innovation in manufacturing**
2. **Advanced manufacturing technology and 3D printing**
3. **Compliance and regulatory expectations for 3D printing**
4. **3D printing case studies:**
   a) Aprecia's ZipDose®
   b) Triastek's MED® 3D Printing
5. **Individualized dosing: Compounding vs. Point-of-Care**
6. **Preparing for FDA submissions**
7. **Summary & Take Aways**

FDA Programs Supporting Innovation

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ETP (2014): Early engagement for novel technologies

AMT (2023): Formal designation with CDER support

FRAME (2023): Risk-based regulatory pathways

Public Workshops & White Papers (2019–2024)

Comparison of ETP and AMT

ETP	Feature	AMT Designation
• Informal consultation	Type	• Formal designation program
• None	Regulatory Benefit	• Yes – expedited review
• No	Public Disclosure	• Yes (if sponsor agrees)
• Informal form	Submission Type	• Formal application
• Early feedback	Intended Outcome	• Regulatory efficiency & confidence
• 3D printing, PAT, modular systems	Example Technologies	• Continuous manufacturing, AI-based control, 3D printing platforms

ETP for concept exploration → **AMT for formal adoption**

3D Printing: Advanced Manufacturing

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Digitally-driven, CAD-based production

Personalized dosing and flexible geometries

Versatility: Centralized or decentralized or on-demand manufacturing

Integration with AI and real-time process control

Regulatory & Compliance Challenges

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Batch definition and traceability (21 CFR 210.3)

Quality and performance of every dose

Validation of digital files and software (GAMP® 5 principles)

Data integrity, audit trails, and cybersecurity

Distributed and decentralized manufacturing quality oversight

FDA Expectations for 3D Printing

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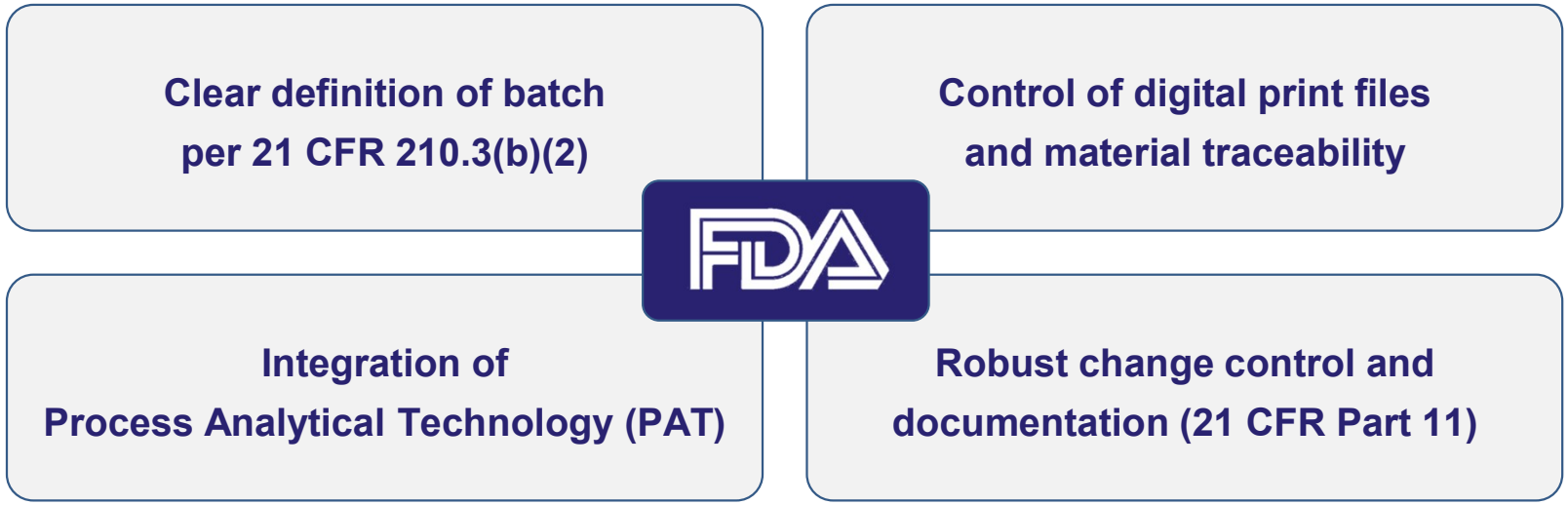

Case Study – Aprecia's Spritam®

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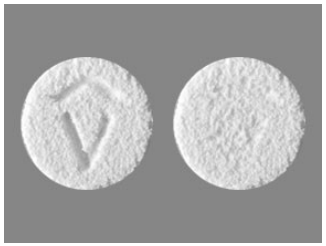
First FDA-approved 3D printed drug (2015)

- Technology: ZipDose® binder jetting
- Dosage form: Fast disintegration & dissolving ODT, high-dose tablet
- Submission: Traditional 505b2 pathway
- Robust validation + CMC package
- Demonstrates regulatory feasibility



Triastek's MED® 3D Printing Platform

- Actively engaged with FDA through ETP
- INDs accepted for multiple programs (e.g., T19, T20G, T21, T22): MR, Gastro-retentive, Colon targeting.
- Batch: Same digital file, printer, continuous run
- PAT-enabled on-line, real-time monitoring

Opportunity in 3D Printing

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Real-Time Release Testing (RTRT)	Justification Needed
• Inline sensors capture CQAs • Control loops for adjustments • Layer shift, voids, print rejection logic • Failure Handling • Faster batch release	• Link digital control to final performance

Comparison of Compounding and POC Concept

Feature	Compounding (Section 503A)	FDA POC concept
Based on prescription?	Yes, must be patient-specific	Not necessarily
Allows individualized dosing?	Yes	Yes
Regulatory oversight?	State pharmacy boards + limited FDA	FDA
Exempt from section 505 & cGMP?	Yes	No, unless a new exemption framework is created
Scale	Small, per prescription	Potential for batch or demand-based production
Manufacturing technology	Traditional (must follow USP chapter on Pharmacy compounding)	Advanced (e.g., 3D printing, continuous manufacturing)
Status	Fully established	Conceptual/under development

Key points

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1. Section 503A: prescription-only, individualized compounding
2. FDA's Point-of-Care concept: broader, scalable, technology-enabled manufacturing near the patient
3. Individualized dosing is a goal of both, but POC might offer more flexibility and scalability — provided a regulatory framework is in place

Preparing for FDA Submission Using MED® 3D Printing Technology

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Early engagement with FDA (ETP & AMT)

CAD-to-product design control

Batch definition + risk assessment

Control strategy: link CPPs to CQAs

Software validation plan

Summary and Takeaways

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1. 3D printing is supported as advanced tech by FDA
2. FDA expects deep scientific justification and digital transparency
3. Batch can be flexibly defined but must be well controlled
4. Compliance must address not only quality but data integrity, software validation, and design traceability
5. Spritam demonstrates regulatory pathways and innovation acceptance

Final Thoughts

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- 3D printing aligns with FDA's vision for advanced manufacturing
- ICH Q13 offers useful structure
- FDA programs provide pioneers the opportunities to shape the regulation
- Success = Early dialogue + Scientific rigor + Strong documentation

References

- 21 CFR 210.3(b)(2), 21 CFR Part 11
- ICH Q13: Continuous Manufacturing of Drug Substances and Drug Products (2021)
- FDA Guidance: AMT Designation Program (2024)
- PAT Framework, Computer Software Assurance (CSA Draft 2022)
- FDA Discussion Papers: Distributed Manufacturing (2021), AI in Drug Manufacturing (2022)
- Draft Guidance for Industry: Considerations for Complying with 21 CFR 211.110 (2025).

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Thank You!

Questions?

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