CATALYZE
Accelerating Translation

Medical Devices-
Crossing the Abyss From Development to Design Lock

Diane Earp
Founder and Principal Consultant
S&D Consulting Services LLC
dearp@sd-consultingservices.com
06/12/2026

CATALYZE
Accelerating Translation

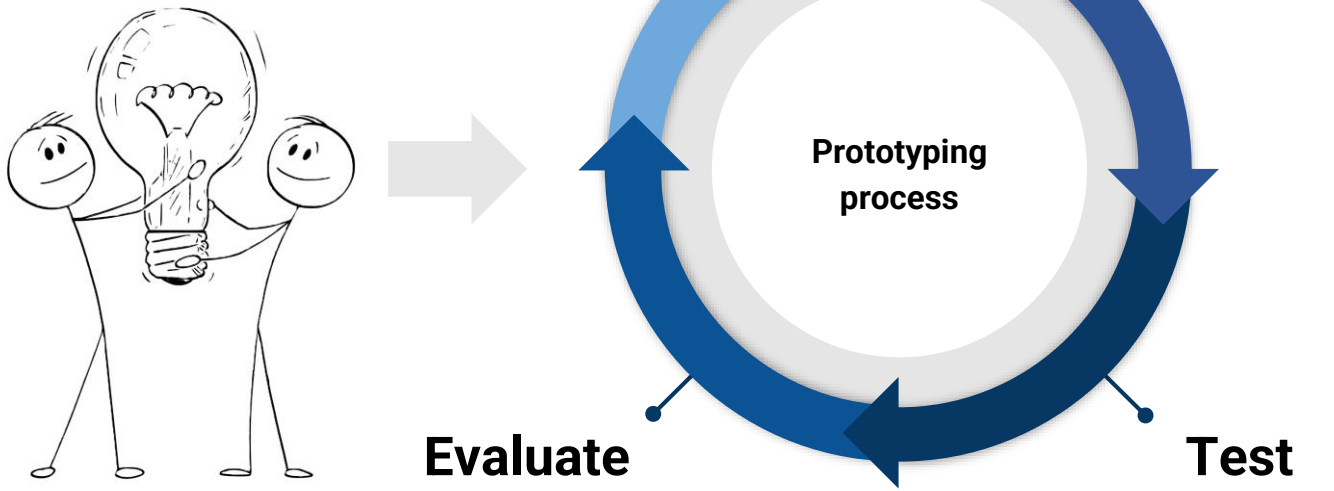
Purpose

Provide a basic understanding of the process of getting *in vitro* diagnostics (IVDs) and therapeutic medical devices (Class II and III primarily) to design lock, and ultimately marketable product status.

Objectives

1. Understand the design lock milestone: What are design controls? How and when does design lock happen?
2. Identify common design pitfalls, their impact on downstream processes and critical market timelines, and how to avoid them.
3. Discuss success factors and solutions for various design scenarios.

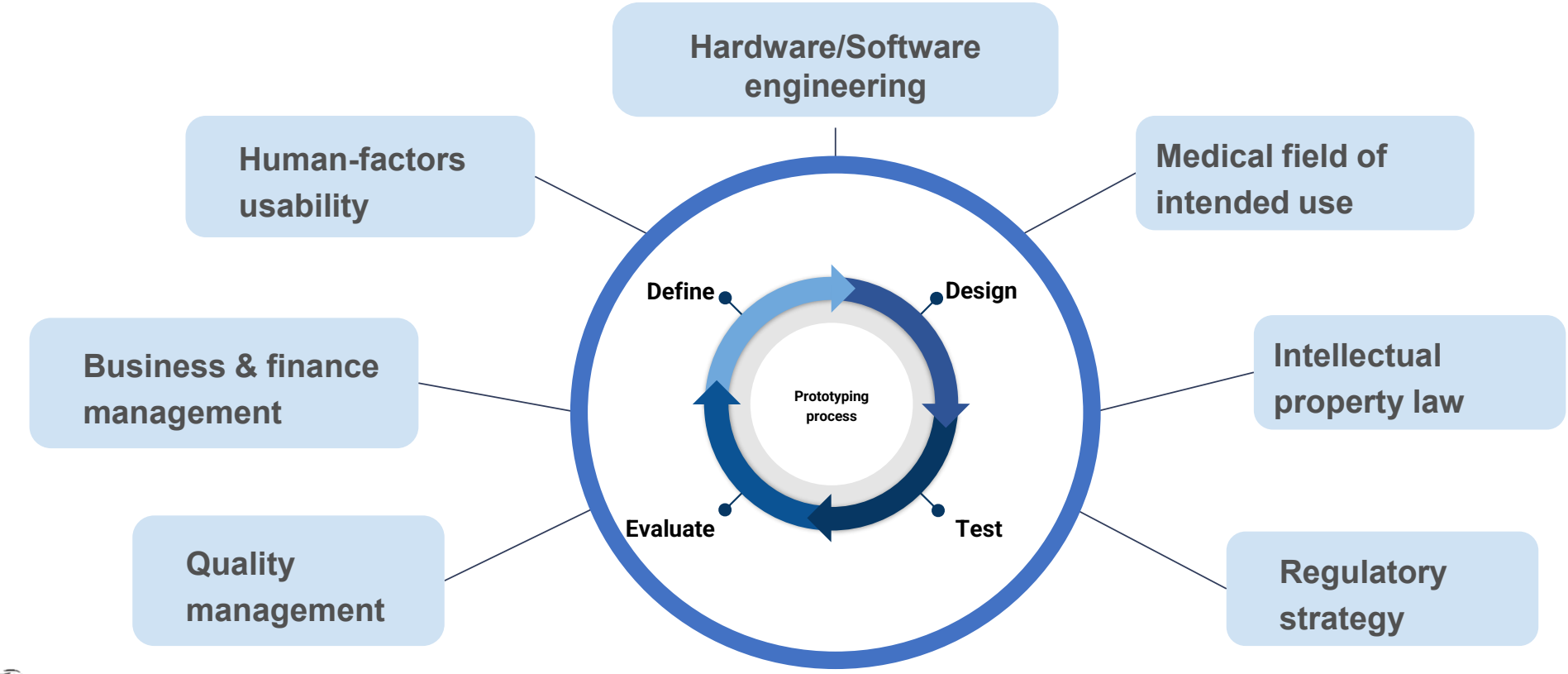
Turning an Idea into a Marketable Medical Device Product

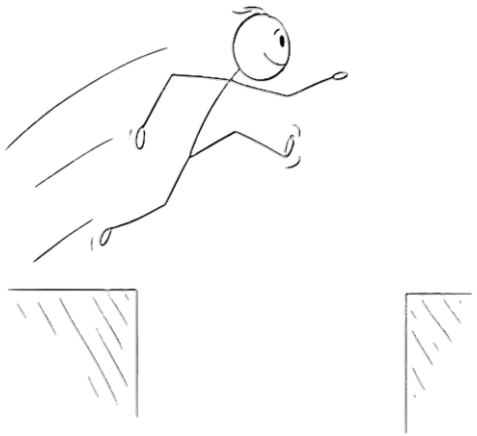


Design process reality: even for Research Use Only (RUO), you can't just take an idea for a device, build a prototype, and attempt to sell it.

The actual ideation-to-market process requires…

Image: File ID 213339057 | Zdenek Sasek| Dreamstime.com





…a complex iterative design process that CAN become a repetitive pitfall into an abyss of everchanging specifications.

General Approach: Concept to Marketable Product

Feasibility Study

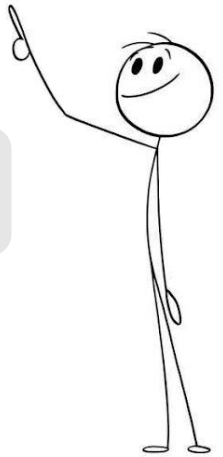
Prototype

Validation & Verification Test Articles

Design Lock

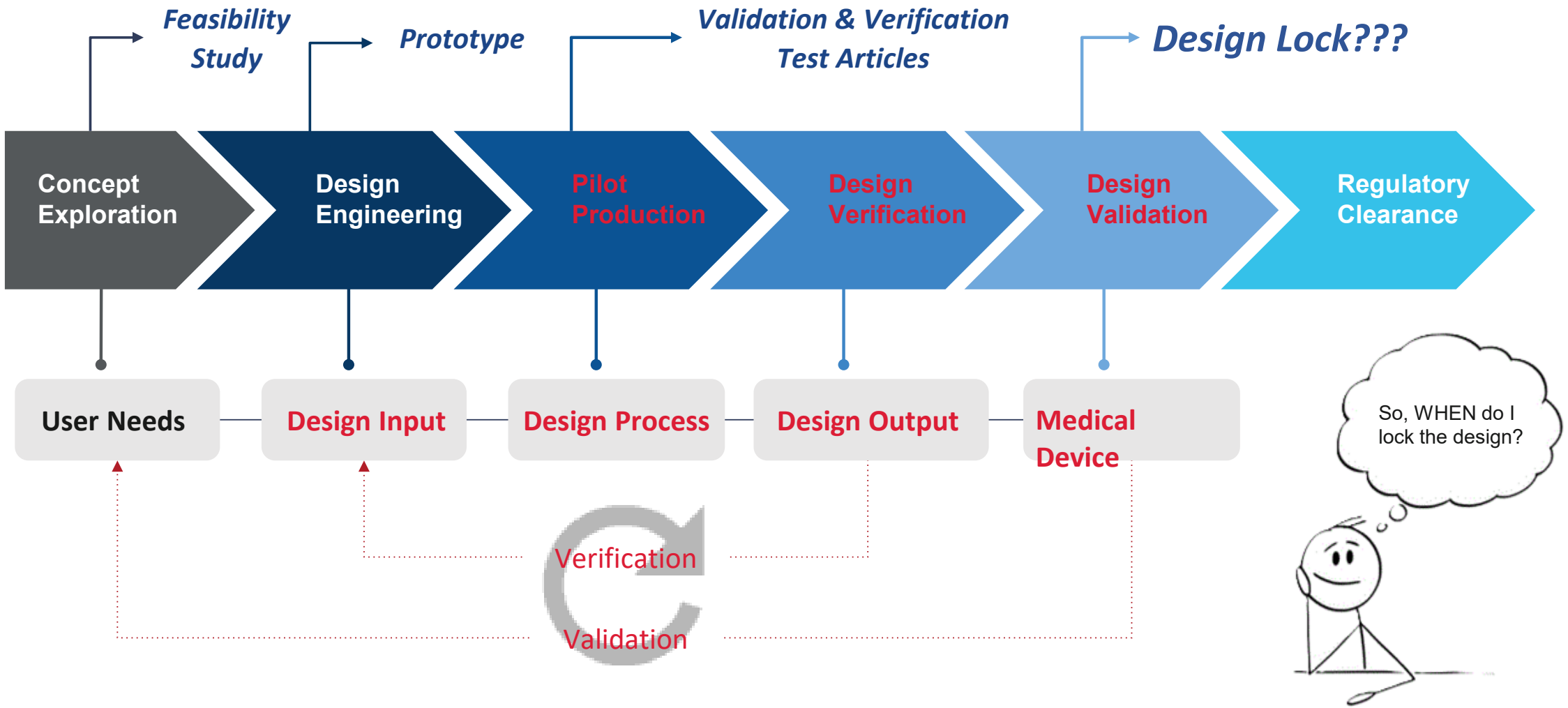
Concept Exploration → Design Engineering → Pilot Production → Design Verification → Design Validation → Regulatory clearance

User Needs — Design Input — Design Process — Design Output — Medical Device



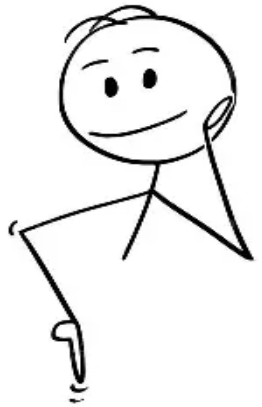
Verification

Validation



***Risk* of continuous redesign conceptually drives failure to pass Design Lock**

What are Design Controls?



- A set of quality practices and procedures that control the design process to assure that the device meets:
  - ***User needs***
  - ***Intended uses***
  - ***Design input requirements***
- Design controls ensure that the device is safe and effective before reaching market.

- Apply to all class II and III medical devices, as well as some class I devices (those that are not GMP exempt), including those automated with computer software.
- Device classification and scope of design controls is driven by a combination of risk analysis and existing defined product codes.

Why Are Design Controls Important?

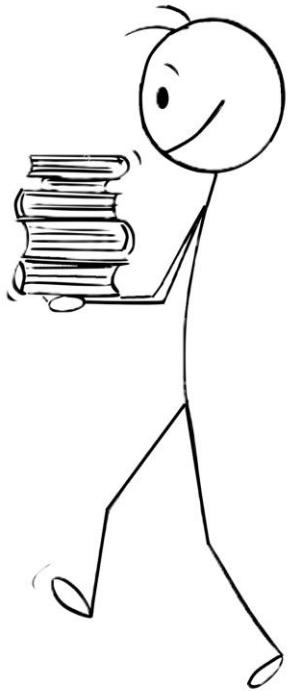
United States Regulatory Requirements

1996 Quality System Regulation (QSR) revision

- FDA formalized design requirements, adapting ISO 9001 principles to the unique risk profile of medical devices.
- 21 CFR 820.30 finalized, currently mandates design controls in present.

February 2026 QSR aligned with international standard (ISO 13485)

- Primarily procedural changes regarding references, training, and risk management.
- Design History File (DHF) is now called Design and Development File (DDF).



Safe Medical Devices Act

Until then, no regulatory mechanisms existed for design control.

⇨ Device failures, patient injuries, and costly recalls.

Evolution of FDA expectations of design controls

- Risk management and human factors/usability become embedded in design controls.
- ISO 14971 and IEC 623XX revisions reflect shift toward stricter review of DHF with respect to risk.

Design controls exist because the medical device industry learned what happens without them.

Why Are Design Controls Important?

Worldwide Regulatory Requirements

EU MDR (Regulation 2017/745) does not have design control requirements, however, Annex II technical documentation requirements including ISO 13485-compliant QMS results in design control.

Health Canada is a MDSAP participant, requiring ISO 13485 compliance for design and development processes.

Therapeutic Goods Association (TGA) is a MDSAP participant requiring compliance with Australian regulatory requirements, aligned with ISO 13485.

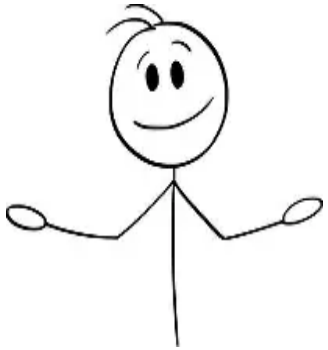
Pharmaceuticals and Medical Devices Agency (PMDA) is a MDSAP participant requiring ISO 13485 for medical device manufacturers.

Agência Nacional de Vigilância Sanitária (ANVISA) is a MDSAP participant requiring ISO 13485 compliance for design and development processes.

Examples of Various Types of Medical Devices Design Controls

Combination Products

- Example is drug-eluting stent.
- Design controls for both device and the drug/biologic components and interactions.
- Requires device-focused (CDRH) and drug-focused (CDER) quality systems and regulatory compliance.



Mechanical Devices

- Example is simple surgical instrument.
- Design controls for materials, measurements, and mechanical performance.
- Requires inspection, testing-based performance.
- Recommend simulated-use studies with surgeons/intended users.

Examples of Various Types of Medical Devices Design Controls

Software as a Medical Device (SaMD)

- Example is diagnostic algorithm.
- IEC 62304 - lifecycle framework for software.
- Design inputs include algorithm performance, cybersecurity, and data handling specifications.
- Clinical performance studies and real-world data needed.

In vitro Diagnostics (IVD)

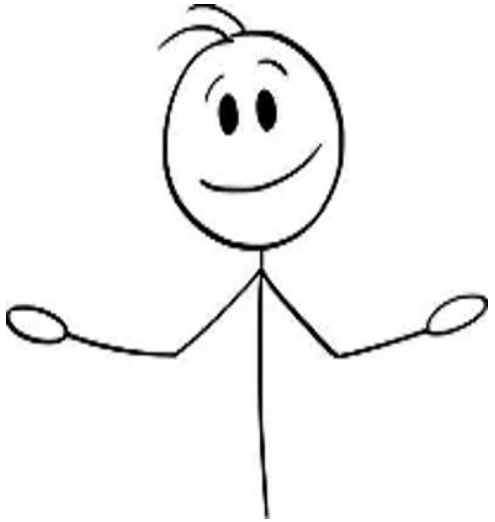
- Example is diagnostic test kit.
- Design controls addressing clinical performance for accuracy, precision, specificity, sensitivity, linearity.
- Under the EU IVDR, performance evaluation requires reagent lot-to-lot consistency evidence.

Electrochemical Devices

- Example is complex imaging system.
- Design controls for HW & SW components, electrical safety, Electromagnetic Compatibility (EMC), human factors, connectivity/cybersecurity.
- Extensive and complex testing across various fields of utility.

What is Design Lock?

- Critical gate in the Design and Development Process.
- A formal milestone requiring approval of final design:
  - The design meets all requirements.
  - Specifications are clearly defined.
  - Prepared to move into manufacturing, supply chain, and regulatory submission.
- Design satisfies applicable regulatory requirements for:
  - Safety
  - Performance
  - Quality



Essentially, all aspects of the design have been validated and approved.

When should Design Lock Happen?

- Typically occurs after design validation is complete and ***before or during design transfer.***
- Requires comprehensive review and signoff by design team, engineering, quality, and regulatory leads along with internal and e[illegible]ers.
- After design lock, changes are now
  - Controlled.
  - Assessed for risk impact.
  - Require formal documented prior approval for implementation.

Image: File ID 221622077 | Zdenek Sasek| Dreamstime.com

Steps taken in typical Design Lock Process

Before

- **Concept & Ideation (Phase 0)**
  Brainstorm and explore ideas without constraints.
- **Design Development**
  Create detailed designs, select materials, and validate performance.
- **Design Verification & Validation**
  Test prototypes, perform risk analysis (e.g., ISO 14971), and ensure compliance with standards and regulations.

Design Transfer

- **Design Review & Approval**
  Internal and external stakeholders review the design for technical, regulatory, and usability aspects.
- **Design Freeze**
  Final sign-off from the design team, engineering, quality, and regulatory leads.

After

- **Transition to Manufacturing**
  Move to reproducibility, tooling, and production planning.
- **Changes are now:**
  - Controlled
  - Assessed for risk impact
  - Require formal documented approval prior for implementation

Key Activities Notoriously Impacting/Delaying Design Lock

- **Transition to CMO or in-house manufacturing**
  - Not Completing the design for manufacturability (DFM).
  - Failure to engage GMP requirements.

- **Suppliers and Materials**
  - Have not finalized bill of materials (BOM).
  - Supplier(s) selection still not confirmed.

- **Sterility & Stability**
  - Failure to perform sterilization validation if applicable (e.g., Ethylene Oxide (ETO), gamma, steam).
  - Failure to initiate stability studies designed to simulate real-time and accelerated storage conditions, considering factors such as temperature, humidity, and light.

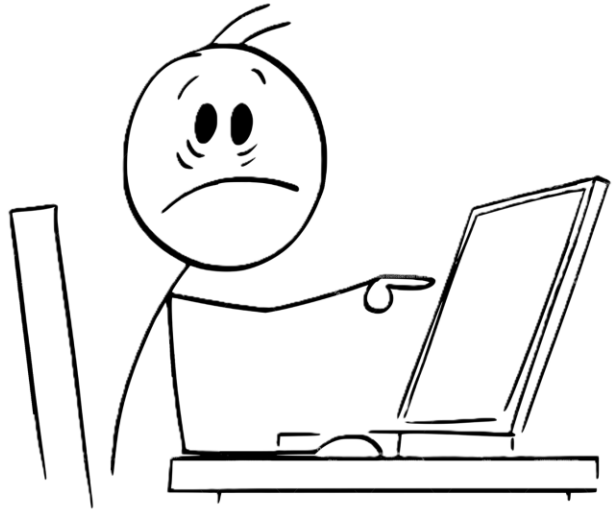
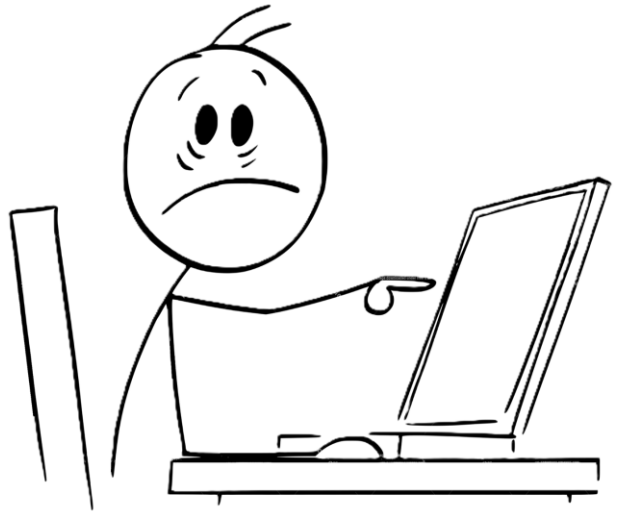


Image: File ID 219988566 | Zdenek Sasek| Dreamstime.com

Key Activities Notoriously Impacting/Delaying Design Lock

- **Legal Issues**
  - Have not ensured IP protection and anti-tampering measures are in place if needed.

- **Lack of Documentation**
  - Not all design decisions can be found in the design and development history file (DDF).
  - No quality management including when to produce under GLP vs GMP vs lab prototyping.
  - No change management plan in place clearly reflecting independent approval processes that include management.

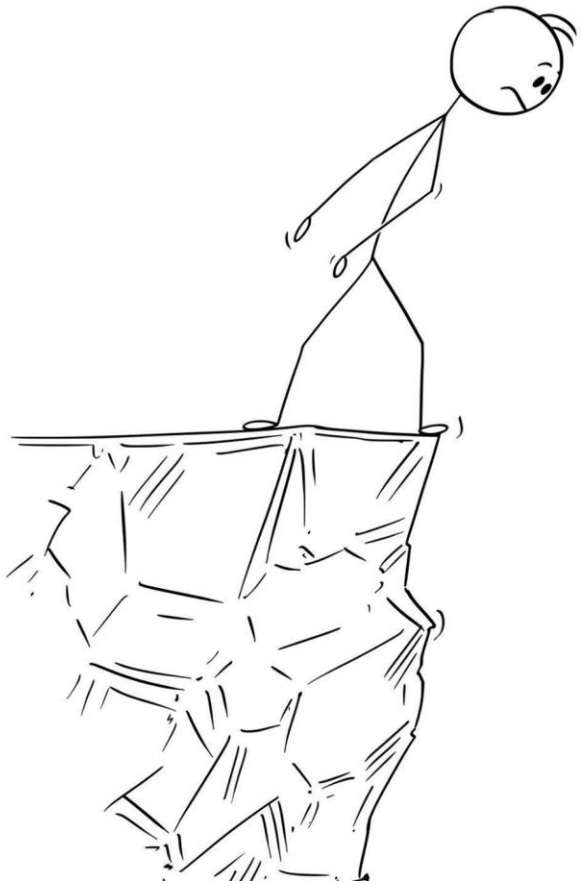


Design Pitfalls to Avoid

- **Critical Misalignment**
  - Between Research & Development (R&D) and Quality Assurance & Regulatory Affairs (QARA) teams.
  - What the engineering team is producing vs. the clinical unmet need.

- **Delaying key activities**
  - Cybersecurity.
  - Required testing.
  - Engagement with regulatory agency.

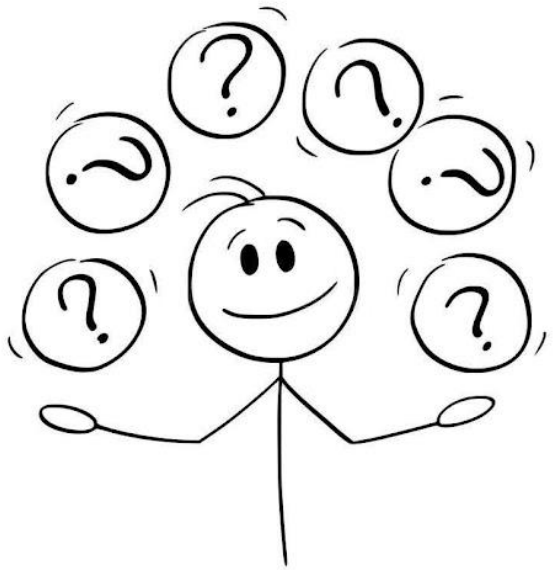
- **Premature advancement**
  - Failure to capture information key design information.
  - Introducing enhancements in late-stage design.
  - Failure to consider change opportunities.



Key Early-Stage Questions

Market

- Is there a significant unmet need for what I am making?
- Patient population?
- Environmental utility/clinical setting/intended use?
- Unmet/under utilized marketable business need?
- Can I produce a cost-effective solution?



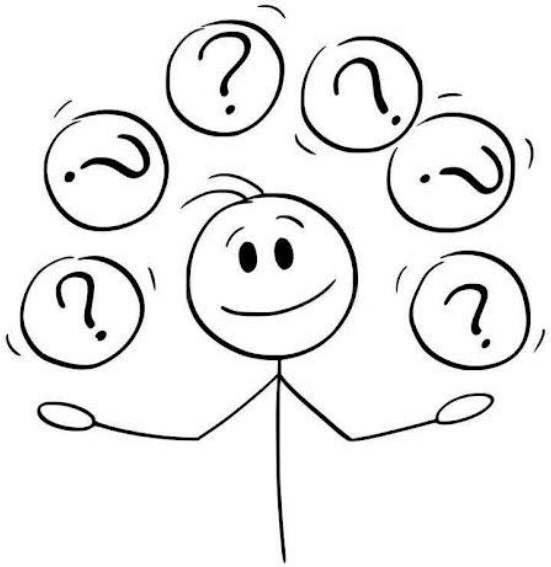
Scalability

- How long/much ($) will it realistically take to
  - Create a prototype and confirm feasibility?
  - Transition to GMP manufacturing?
- Is the device reproducible on a large enough scale to meet
  - Patient need?
  - Business need?

Key Early-Stage Questions

Project Outcome

- R&D or product development?
- Publications, seminars, professional meeting symposiums and poster sessions?
- Engaging venture capitalists, translational science grants, other types of investors?
- Sell your technology or start a business?



Risk Management

- How much risk comes with this diagnostic result or device performance?
- Patient impact?
- User-side human factors risk?
- Liabilities for false results?
- Infringement on existing devices IP?
- Reimbursement and payer ID?

Image: File ID 354635487 | Zdenek Sasek| Dreamstime.com

Example Scenarios

Yes, they really happen…….

Image: File ID 239710341 | Zdenek Sasek| Dreamstime.com

Scenario 1

In Vitro Diagnostic Device developed in the research lab repeatedly showed great performance when produced and tested by the inventor.

- **Background**
  - Each device took 1-2 weeks to build in the lab.
  - Clinical labs were contracted to begin doing testing and showed excellent performance.
  - Need for multiple devices in a timely manner led the team to move the "near design lock."
  - prototype design to an expensive but recommended CMO several states away.

- **Status**
  - Commitment to produce 50+ devices was contracted with the CMO.

- **Unexpected Event**
  - Devices never made it out of the GMP environment as reproducibility could not be acquired to meet the specifications.
  - After multiple runs, the inventor accepted the devices and took the failed devices to the Research lab for rework. Unfortunately, clinical testing results were inconsistent on the reworked devices.
  - Repeated trips by the inventor and staff to the CMO to review the specifications, manufacturing plan, and train staff did not resolve the issue, and additional funding was needed to continue the project and identify a new CMO.

What went wrong and what do they do now?

Scenario 2

A De Novo device for early detection of a critical disease state was showing promising results not seen in the commercial marketplace.

- **Background**
  - Great interest from companies with the current state of later stage diagnostic products.
  - Inventor was passionate about the product and began publishing articles, attending symposiums, and talking with various device companies sharing openly the technological approach and results.
  - Success was obvious and his team was well funded to take the device to the next stages of development and ultimate productization.

- **Status**
  - Reluctant to move into design lock.
  - Felt there was more development that could be done to enhance the design.
  - Wanted to produce and publish additional findings.

- **Unexpected Event**
  - Encouragement to engage with FDA and establish a regulator pathway forward was met with resistance as the inventor felt it wasn't ready.
  - Funding started to dwindle and grad students supporting effort graduated and moved on.

What went wrong and what do they do now?

Image: File ID 140121864 | Zdenek Sasek| Dreamstime.com

Scenario 3

A device for an unmet need was now in design lock, had engagement with FDA a year earlier in the development stage, and was confident the product was going to be a De Novo Submission.

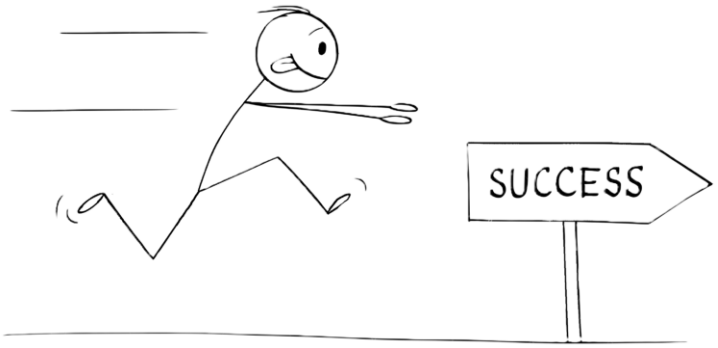
- **Background**
  - Work was underway to acquire the needed testing and validation to support the submission package.
  - Lack of funding had delayed progress.
  - Now 2 years behind the defined timeline for an FDA submission.
  - No additional FDA Q Sub meetings or review of the regulatory or business strategy had occurred.
  - Not sure about the quantity of clinical data needed but were gathering what they could under the financial constraints.
- **Status**
  - Attempting to build the structure for the new business and diverting funds to hiring key personnel full time.
- **Unexpected Event**
  - They identified a new device had been approved by FDA that was significantly equivalent to their device.

What went wrong and what do they do now?

Factors Leading to Successful Design Lock

- **Timing of tasks/actions and end game are critical to get recognized success.**
  - For Research Use Only?
  - Sell technology for licensed use or outright purchase?
  - Build a business to support first generation and later stage products for broader util

  ➔ Selling too early can result in significant financial lo
  Too late, and you've spent unnecessary $.



- **Business plan and regulatory strategy integration is a mu**
  - Regulators.
  - Investors.
  - Market analysis.
  - Timeline alignment.

- **Managing device risk throughout the life cycle of development and beyond is critical.**

In Summary

Crossing the Design Lock Abyss can be easy, provided you have a clearly-defined, disciplined approach that includes an integrated technical proposal, regulatory and commercialization strategy and a thoughtful business plan to reach your endpoint– whether that is selling your new technological discovery or building a business to support patient access to your innovation.

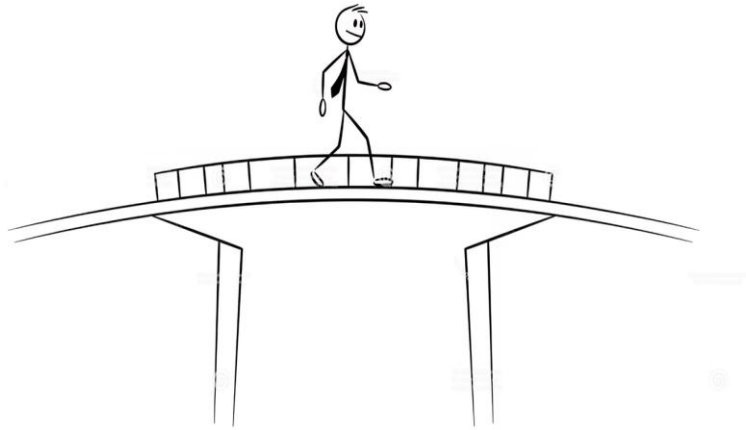
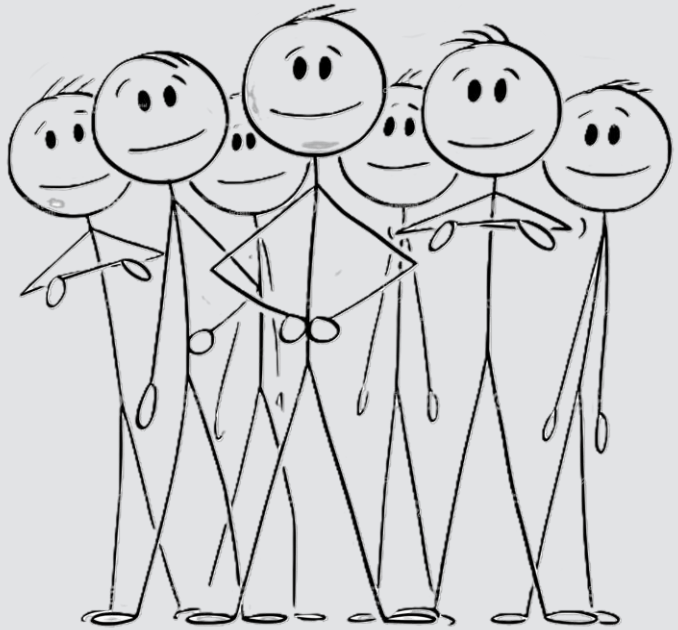


Image: File ID 436410004| Hikari Hikari| Dreamstime.com

CATALYZE
Accelerating Translation



Any Questions?

Research Triangle Institute
Catalyze Coordinating Center
304 East Cornwallis Road
Durham, NC 27713

Catalyze-info@rti.org
NHLBI_catalyze@nih.gov

Regulatory Resources

CDRH Learn - Multi-Media Industry Education

Over 115 modules videos: audio recordings, powerpoint presentations, software-based "how-to" modules

http://www.fda.gov/Training/CDRHLearn

Device Advice – Text-Based Education

Comprehensive regulatory information on pre-market and post-market topics

http://www.fda.gov/DeviceAdvice

Division of Industry and Consumer Education (DICE)

Contact DICE if you have a question

DICE@fda.hhs.gov

1-800-638-2041 or (301) 796-7100

http://www.fda.gov/DICE

Reference Materials

Medical Devices; Quality System Regulation Amendments. Federal Registry. (2026, February 2). https://www.federalregister.gov/documents/2024/02/02/2024-01709/medical-devices-quality-system-regulation-amendments.

CDRH. (2025, May). *Electronic Submission Template for Medical Device Q-Subs Guidance*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions.

CDRH. (2025, July). *Small Business Qualification and Determination*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination

CDRH. (2025, October). *QMS Information for Certain PMA Reviews Draft Guidance*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-management-system-information-certain-premarket-submission-reviews.

Reference Materials

CDRH. (2022). *Content of Human Factors Information in Medical Device Marketing Submissions*. Www.fda.gov. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions.

CDRH. (2025, May 11). *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

CDRH. (2025, December). *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices.

Vernon, M. (2020). *Design Controls Cultivating Compliance Virtual Conference*. https://fda.report/media/142013/MatthewVernon%252BDesign%252BControls%252BPresentationFINAL.pdf.

CDRH. (2026, February). *Cybersecurity: Quality System Considerations and Premarket Submissions*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket.

Reference Materials

CDRH. (2025, May). *Electronic Submission Template for Medical Device Q-Subs Guidance*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions.

CDRH. (2025, July). *Small Business Qualification and Determination*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination

CDRH. (2025, October). *QMS Information for Certain PMA Reviews Draft Guidance*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-management-system-information-certain-premarket-submission-reviews.

CDRH. (2026, February). *Cybersecurity: Quality System Considerations and Premarket Submissions*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket.

Image Attribution

Zdenek Sasek | Dreamstime.com

Hikari Hikari | Dreamstime.com

Mst Aleya Khatun | Dreamstime.com

Stock.adobe.com

Flaticon.com