Matrix One + Follow

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12 Tips for better Design control

12 tips to apply in your Design & Development process for Medical Device

1 Start with a clear D&D Plan

Use a simple, **flexible plan document** from the beginning to define stages, responsibilities, and **update it iteratively.**

2 Map requirements to user needs

For every user need, create **traceable design inputs**. Use a traceability matrix to link needs → inputs → outputs → tests.

3 Differentiate Inputs from Outputs

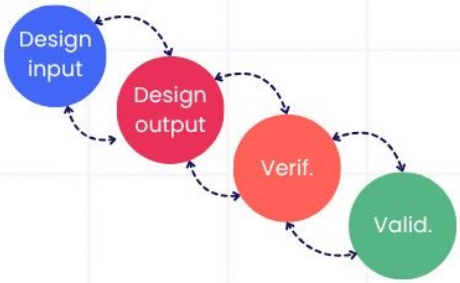
Design inputs describe what the **product must do**; outputs show how the product **achieves those goals**. Keep them distinct.

4 Use unique identifiers

Assign **unique codes or IDs** to each requirement, test, spec, and document to ensure traceability across systems.

5 Use a living traceability matrix

Keep a centralized, version-controlled **traceability matrix** updated continuously from concept to validation.



6 Avoid jumping to solutions

Record **design inputs** as **performance needs** (e.g., "needs 15 lumens of light") not pre-defined solutions ("use 8V battery").

7 Document iterations explicitly

When a verification or validation **fails**, **log changes** and clearly mark the new input/output versions linked to the tests.

8 Integrate risk management

Link each **input/output** to corresponding **risks** (when possible) and **risk control measures** under ISO 14971 update both together when changes occur.

9 Version control everything

Track versions of every document. Never overwrite; archive old versions with comments on changes and reason.

10 Design freeze with rationale

When **freezing** a design, log **rationale**, approved drawings, and testing implications. Freeze only when V&V can proceed safely.

11 Link verification to inputs

Each test in the **verification protocol** must clearly trace back to the design input it is proving.

12 Train team on traceability concepts

Ensure every team member understands document types, **traceability importance**, and their role in maintaining it.

User Needs ↔ Req #1 ↔ Design item #60 ↔ Verif test #42 ↔ Risk #78 ↔ Clinical #58

Use an ALM in your design control

Matrix Req

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