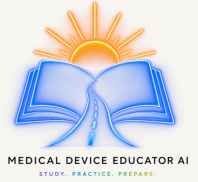


MDEAI • *Medical Device Educator AI*

Revolutionize Medical Device Education.



The next generation of medical-device engineers is being trained on textbooks and simulations. They graduate having never touched a real Design History File. Their first day at Medtronic or Boston Scientific is their first day with the artifact stack the industry actually runs on. *That gap is expensive* — for the employer, for the graduate, and for the pace of innovation the field promises.

MDEAI closes the gap. Students get the industry platform, faculty-scoped. Every case-study device becomes a real DHF that students build over a semester — same personas, same citations, same review discipline as the practicing engineer. *Faculty review the artifact, not grade a template.* The portfolio a student leaves the program with is one a hiring manager can actually evaluate.

WHO IT'S FOR

Biomedical engineering programs teaching medical-device commercialization — where the capstone deserves better than a bound report nobody reads after graduation.

Bioengineering + Materials Science programs with device-focused capstone projects — give the students a real DHF workflow, not a Google Doc pretending to be one.

University Med-Device Innovation Centers running multi-team incubators — every team on the same platform, faculty-scoped rollups, real classification for real ideas.

STUDENT WORKSPACE • DHF

SEMESTER PROJECT

Continuous glucose monitor • team 4

PROGRESS	Week 9 • 62%
CLASS	II • 510(k) pathway
PREDICATE	K201234 • cited
FACULTY	Dr. Chen • reviewer

Submit for review

✓ Auto-cited

INSTRUCTOR • COHORT VIEW

FACULTY DASHBOARD

BME 402 • Fall • 24 students

Reviewer / approver primitive • rubric-linked

"Team 4 flagged a substantial equivalence gap on their predicate. AI tutor cited 21 CFR 807.87(f) with the specific requirement. Ready for your review."

Review submission

Rubric

EVERY CASE-STUDY DEVICE, ONE PLATFORM

The industry stack, faculty-scoped.

MDEAI is the same platform depth as MJAI (the industry product), reshaped for the classroom. Students draft artifacts the practicing engineer would recognize; instructors review the outputs of a real workflow, not a rubric-shaped simulation. **The portfolio graduates as a real DHF, not a case study.**

● MULTI-FACULTY TENANTS	BME · BioChem · Materials · ME cross-program rollups. Dean-level views across every active section — and section-level isolation for each course's students.
● STUDENT WORKSPACES	One tenant per case-study device. Semester-long; carries the DHF through classification, design controls, V&V, and Q-Sub compile. Students exit with a real artifact.
● INSTRUCTOR REVIEWER	First-class reviewer / approver primitive — rubric-linked, comments-in-context, cohort dashboards. <i>Grade the artifact, not a template.</i>
● CITATION-FIRST TUTOR	Every AI recommendation grounded in source regulation — 21 CFR, ISO, FDA guidance, ISO 14971. Students learn WHY a rule applies, not just that it does.
● FULL PLATFORM DEPTH	Same Design Controls, Process Controls, Submit, Monitor surfaces as MJAI. <i>Not a training-wheel version</i> — the industry stack, in a curriculum-shaped tenancy.
● PORTFOLIO EXPORT	Student takes their DHF, Q-Sub package, and traceability matrix with them when they graduate. Hiring managers evaluate the actual work, not a resume line.
● CURRICULUM KITS	Pre-loaded case-study devices spanning IVD, orthopedic, cardiovascular, ophthalmic. Or bring your own — the platform scaffolds new devices in minutes.
● CROSS-COHORT ROLLUPS	Department chair sees classification distributions, common gaps, teaching-moment friction points across semesters — the data every program dean wishes they had.

WHAT YOU STOP BUYING

Labster life-sciences simulations · single-vendor curriculum packages · adjunct-instructor time drafting original case studies · student-managed Google Drives that die at semester end · **textbooks the students sell back in June.**

See bollong.ai for details. Faculty pilots for the Fall term open in June.