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Risk Assessment Worksheet

The Universal Compliance Pathway · Set specifications, then perform a risk assessment (ICH Q9)

Every regulated cannabis regime — DEA Schedule III, a new state market, FDA, EU export — reduces to the same two moves: set specifications (your Critical Quality and Safety Attributes), then run a risk assessment against them. This worksheet walks that method end to end. Fill it for one product, substance, or process line; duplicate the register rows as needed. Companion to the essay "One Pathway, Every Regulator" at intrepidscientific.com/universal-pathway.

1. Scope & Intended Use

Define what you are assessing and which rulebooks apply. This is the only step that changes when a new regulator appears.

1.1 Operation / legal entity and site(s) covered by this assessment.

1.2 Product(s), substance(s), or process line(s) in scope.

1.3 Regulators & markets in scope (check all that apply). Each adds rows to the specification register in Section 2.

- ☐ DEA Schedule III (21 CFR 1301.13(k))
- ☐ State adult-use market
- ☐ EU GMP / export (Annex 7, QP)
- ☐ Customer / contract GMP audit
- ☐ State medical market
- ☐ FDA (Part 211 / IND-NDA)
- ☐ ISO/IEC 17025 (lab)
- ☐ Other:

1.4 Assessor

2. Specification Register (CQAs / CSAs)

Translate every applicable requirement into one measurable specification: the Critical Quality Attribute (CQA) or Critical Safety Attribute (CSA), its test method, and its acceptance criterion. Where two regulators differ, record the highest common bar.

#	Requirement source (rule / regulator)	Specification — CQA / CSA (test method)	Acceptance criterion	Status

3. Risk Assessment Register (ICH Q9)

For each specification and process step, score the risk of non-conformance. Risk Priority Number (RPN) = Probability x Severity x Detectability. Rank, then act worst-first.

Probability (P): 1 Rare 2 Unlikely 3 Possible 4 Likely 5 Almost certain
Severity (S): 1 Negligible 2 Minor 3 Moderate 4 Major 5 Critical (patient / regulatory)
Detectability (D):1 Almost certainly caught before release … 5 Unlikely to be caught before release
RPN = P x S x D (range 1–125). Suggested action: 1–12 monitor · 13–29 control · 30+ priority remediation (Section 4).

#	Requirement / spec (CQA / CSA)	Hazard / failure mode	P	S	D	RPN	Existing controls	Owner

4. Risk Control & Remediation Plan

For every risk above the action threshold, define the additional control, the residual risk after it is in place, and who owns it by when. Controls trace back to a risk number and a specification.

Risk #	Additional control / remediation action	Residual RPN	Owner	Due	Status

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5. Verification & Lifecycle

Confirm controls work, then keep them working. This is where recurring obligations live — DEA biennial inventory, state annual audit, periodic management review.

5.1 How was the effectiveness of the controls verified? (validation, audit, monitoring data)

5.2 Recurring obligations & cadence (e.g., annual CCA audit, biennial DEA inventory, periodic review).

5.3 Next review date

5.4 Change that would trigger an earlier review

Assessor (name / signature)

Quality approval (name / signature)

Date