



LANDRY INDUSTRIES INC. · MATERIALS & BIOMEDICAL RESEARCH DIVISION

HEMPOXY MECHANICAL ONCOLOGY PLATFORM

Master Research & Development Blueprint — Phases 0 through IV

REVISION	2.0 — enhanced & source-verified edition (supersedes Rev 1.0, 5 Oct 2026)
PRINCIPAL	Marie Landry, CEO & Founder · ORCID 0009-0008-5027-3337
LOCATION	Moncton, New Brunswick, Canada
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CLASSIFICATION	Pre-disclosure working document — review IP section before public posting

STATUS · TRL 1–2. This blueprint describes a forward-looking research hypothesis. Every performance figure, geometry and timeline in it is a *projected design target*, not a validated result. No Hempoxy device has been fabricated or tested on cells, animals or humans. Nothing here is medical advice or a claim of therapeutic effect.

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WHAT CHANGED FROM REVISION 1.0

AREA	REV 2.0 ENHANCEMENT
Scientific grounding	Added peer-reviewed precedent for mechanical (non-chemical) cancer-cell destruction — molecular drills, molecular jackhammers, magnetic-vortex microdiscs, and FDA-authorized histotripsy — so the concept is positioned within an established field.
Selectivity	Named the central open question (how a physical tool spares healthy cells) and proposed a measurable <i>mechano-selective window</i> hypothesis built on published AFM evidence that cancer cells are softer.
Testing standards	Corrected: ASTM D638 covers unreinforced/neat plastics; fibre-reinforced composites use ASTM D3039. Added ASTM F602 and ISO 10993-1:2025 for biocompatibility.
Scale realism	Flagged that hemp bast fibres (tens to hundreds of μm) are as large as or larger than a cancer cell, so fibres can reinforce the array backing but not the cell-contacting tips.
Plan structure	Added Phase 0, quantitative go/no-go gates, a Gantt timeline, a risk register, and a regulatory/ethics pathway.
IP protection	Added a disclosure warning: open posting (Zenodo, Scribd, GitHub) before filing can destroy patent rights in absolute-novelty jurisdictions and only partly survives Canada's 12-month grace period.

01 EXECUTIVE SUMMARY

The Hempoxy Mechanical Oncology Platform proposes to destroy malignant cells *physically* rather than chemically, using microneedle and nanostructured arrays made from hemp-derived epoxy composites and guided in real time by AI-interpreted electrical impedance.

THE PROBLEM

Chemotherapy and many targeted biological therapies act through molecular pathways that tumours can evolve around — drug efflux, target mutation, pathway redundancy — and they reach healthy tissue through the bloodstream, producing systemic toxicity. A mode of killing that does not depend on a molecular target would in principle be much harder for a cell to become resistant to.

THE PROPOSED SOLUTION

Engineered micro- and nanostructures ("Hempoxies": hemp-fibre and hemp-carbon reinforced bio-based epoxy, with titanium or stainless-steel tips where rigidity demands) apply controlled mechanical stress that ruptures cancer-cell membranes (*mechanical lysis*). Electrical impedance spectroscopy (EIS) reads the state of the tissue continuously; a machine-learning classifier inside a deterministic safety envelope decides where, how hard and how fast the array acts.

4+1

phases (0–IV)
over 18 months

5

falsifiable core
hypotheses

6

go/no-go gates
with criteria

3

patent families
targeted

WHAT MAKES THIS CREDIBLE — AND WHAT IS STILL UNPROVEN

SUPPORTED BY LITERATURE

- Mechanical action can kill cancer cells: molecular drills (2017), molecular jackhammers (2023), and magnetic microdiscs (2010) all did so in the lab.
- A mechanical tumour-destruction device is clinically authorized: histotripsy received FDA De Novo authorization for liver tumours in October 2023.
- Cancer cells from patient samples were measured to be markedly softer than benign cells (AFM, 2007).
- Hemp can supply both an epoxidized bio-oil resin and high-performance carbon nanosheets.

UNPROVEN — THE WORK OF THIS PLAN

- That a *solid needle array* can lyse cancer cells selectively while sparing healthy neighbours.
- That a hemp-epoxy composite can hold a sub-micrometre tip and survive sterilization.
- That the cured composite passes ISO 10993 biocompatibility tests.
- That impedance signatures can locate tumour cells reliably enough to steer the device.

STRATEGIC RECOMMENDATION

Treat Phases 0–II as a self-contained, publishable materials-and-bioengineering programme with value even if the oncology hypothesis fails: a validated hemp-epoxy microneedle and a tumour-on-chip impedance testbed are useful products in their own right. File provisional patents *before* any public posting.

02 SCIENTIFIC PRECEDENT: MECHANICAL ONCOLOGY IS REAL

Hempoxy does not need to prove that physical force can kill cancer cells — that has already been shown, at several scales. Its contribution would be a new *material* (bio-based composite), a new *form* (contact microneedle arrays) and a new *control layer* (impedance-guided AI). The table below places the platform among published approaches.

APPROACH	SCALE	WHAT WAS SHOWN	LESSON FOR HEMPOXY
Histotripsy (HistoSonics Edison)	Tissue, mm	Focused ultrasound creates acoustic cavitation that mechanically liquefies targeted tissue, non-thermally. FDA De Novo authorization for liver tumours, 9 Oct 2023. ^[1]	Regulators will authorize a purely mechanical oncology device; De Novo is the route when no predicate exists.
Molecular drills (García-López et al.)	Molecule, nm	Light-activated rotary molecular motors drilled through cell membranes and killed cells within minutes. ^[2]	Membrane rupture by nanoscale motion is enough to kill a cell.
Molecular jackhammers (Ayala-Orozco et al.)	Molecule, nm	Near-infrared light drives whole-molecule vibration of aminocyanine dyes bound to membranes; ~99% of cultured human melanoma cells killed, and half of treated melanoma-bearing mice became tumour-free. ^[3]	Mechanical killing can work in vivo; targeting came from membrane binding, not from the force itself.
Magnetic-vortex microdiscs (Kim et al.)	Particle, ~1 µm	Antibody-coated permalloy discs (~1 µm × 60 nm) oscillated by a low-frequency field (tens of Hz) applied piconewton forces that triggered death in ~90% of targeted glioma cells. ^[4]	Very small forces can be enough when applied <i>to the right cell</i> ; the force can trigger programmed death rather than outright rupture.
Cancer-cell nanomechanics (Cross et al.)	Cell, µm	AFM on cells from patients' pleural fluid: metastatic cancer cells were much softer than benign cells from the same specimens, and the two groups' softness values did not overlap. ^[5]	A physical difference exists that a mechanical tool could, in principle, exploit for selectivity.

POSITIONING STATEMENT

Hempoxy is a **contact-mode, material-defined** member of the mechanical-oncology family. Its closest relatives achieve selectivity through targeting (antibodies, membrane-binding dyes) or through image guidance (histotripsy). Hempoxy's proposed differentiator is selectivity through **mechanics plus sensing** — which is exactly the claim the programme must test first.

03 THE SELECTIVITY PROBLEM & TESTABLE HYPOTHESES

A needle does not know which cell it touches. Rev 1.0 claimed that mechanical lysis "bypasses biochemical resistance" — true, but it also bypasses the biochemical *selectivity* drugs offer. The scientific heart of this platform is therefore one question: **is there a force window that ruptures cancer cells but not healthy ones?**

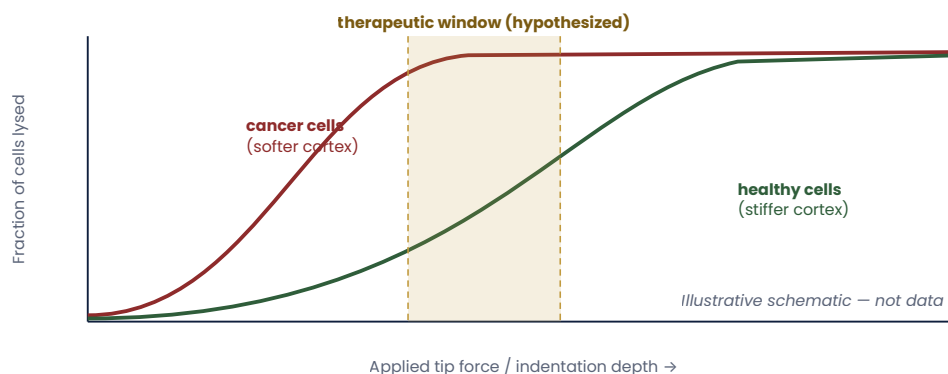


Figure 1. The mechano-selective window. If dose–response curves for malignant and healthy cells separate, a controller can operate between them. Measuring whether, and how widely, they separate is the first deliverable of Phase II.

KNOWN COMPLICATION

Individual cancer cells tend to be softer, but tumour *tissue* is often stiffer than normal tissue because of a dense, cross-linked extracellular matrix. A needle that enters a tumour therefore meets stiff matrix first and soft cells second. Spheroid and organoid models must include stroma, or results will overstate selectivity.

CORE HYPOTHESES (EACH WITH A KILL CRITERION)

H1 Separation. For at least one tip geometry, the force producing 50% lysis (F_{50}) in malignant cells is at least twofold lower than in matched non-malignant cells.

Falsified if F_{50} ratios across three cell-line pairs fall below 1.5.

H2 Material. A hemp-epoxy composite can be micromoulded into needles whose tips keep their sharpness after 1,000 insertion cycles into a tissue phantom.

Falsified if tip radius more than doubles, or fracture rate exceeds 5%, versus a commercial polymer control.

H3 Biocompatibility. Fully cured Hempoxy extracts are non-cytotoxic under ISO 10993-5 conditions.

Falsified if cell viability falls below 70% of control (the usual ISO 10993-5 cut-off) for any formulation that meets H2.

H4 Sensing. Multi-frequency impedance distinguishes malignant from healthy spheroid regions with AUC ≥ 0.90 on held-out spheroids.

Falsified if AUC stays below 0.80 after feature engineering, or results do not survive spheroid-level cross-validation.

H5 Debris control. A chitosan coating (cationic) binds anionic cell debris such as DNA and reduces the inflammatory signal released after lysis.

Falsified if released nucleic-acid or inflammatory-marker levels do not fall by at least 30% versus uncoated arrays.

04 MATERIALS ARCHITECTURE

Hempoxy is best understood as a **hierarchy**: different hemp-derived ingredients do different jobs at different length scales. Rev 1.0 treated "hemp-fibre reinforced epoxy" as one material; Rev 2.0 assigns each ingredient to the scale it can physically serve.

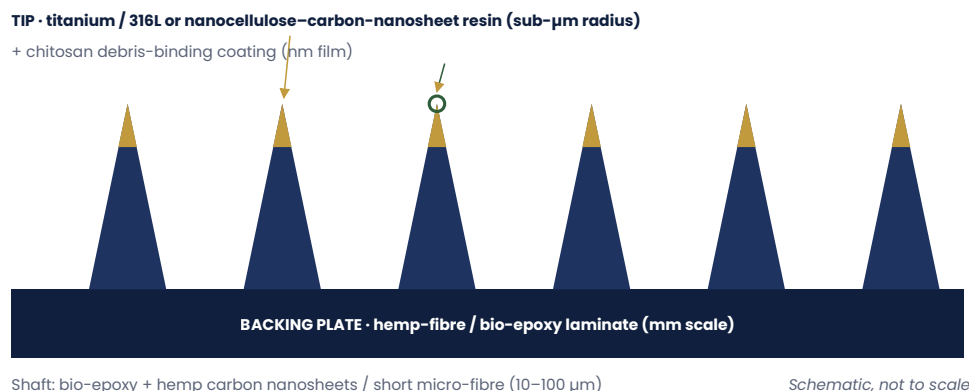


Figure 2. Proposed hierarchical layout. Each hemp-derived input is assigned to the length scale it can serve.

COMPONENT	SCALE	ROLE & EVIDENCE	KEY RISK
Bio-based epoxy matrix	Continuous	Epoxidized hemp oil (EHO) can partially replace petroleum epoxy: Manthey et al. found EHO bioresins slightly outperformed epoxidized soybean oil, but only below about 30% replacement, with synthetic epoxy still strongest. [6] Plan for a <i>hybrid</i> resin.	Lower stiffness and T_g at high bio-content; residual monomer leaching.
Hemp bast fibre	Tens to hundreds of μm	High specific strength for the backing laminate. Fibres in published micro-tomography studies span roughly 40–200 μm in diameter ^[7] — comparable to or larger than a 10–20 μm cancer cell.	Too coarse for tips; moisture uptake; batch-to-batch variability.
Hemp-derived carbon nanosheets	nm-thick sheets	Wang et al. converted hemp bast fibre into interconnected carbon nanosheets with graphene-like properties. [8] Candidate nano-reinforcement for tips and shafts, and a conductive path for on-needle impedance electrodes.	Unknown cytotoxicity of carbon nanomaterial wear debris.
Metallic tips (Ti, 316L)	μm –sub- μm	Established implant metals with proven machinability. Fallback whenever a polymer tip cannot hold its radius.	Reduces "bio-based" share; hybrid bonding interface.
Chitosan coating	nm film	Cationic polysaccharide that binds anionic species such as nucleic acids; proposed to capture lysis debris (H5).	Coating durability on insertion; sterilization effects.
Biodegradable / vitrimer variant	Matrix	Links to the Hempoxies vitrimer programme: dynamic covalent networks could allow controlled degradation of a left-behind array.	Degradation products need their own ISO 10993 evaluation.

BIOCOMPATIBILITY BASELINE

ASTM F602 sets criteria for implantable thermoset epoxy plastics derived from bisphenol-A diglycidyl ether (DGE-BPA), and applies only to *fully cured* material; it explicitly does not establish that any formulation is implantable.^[9] A hemp-oil epoxy falls outside its chemistry, so Hempoxy must build its own biological evaluation under **ISO 10993-1:2025**, published November 2025, which now places biological evaluation inside an ISO 14971-style risk-management process and requires attention to reasonably foreseeable misuse.^[10]

MECHANICAL TEST STANDARDS (CORRECTED)

ASTM D638 (tensile properties of plastics) applies to the neat and hybrid resins. **ASTM D3039/D3039M** (tensile properties of polymer-matrix composites) applies to the fibre-reinforced backing laminate.^[11] Neither describes a micro-needle; tip performance needs bespoke tests — insertion force into calibrated phantoms, buckling load and SEM tip-radius tracking — documented carefully enough that they can later become a published method.

05 DEVICE CONCEPT & PROJECTED TARGET SPECIFICATIONS

The device has three subsystems: the **array** (the needles), the **actuator** (what moves them), and the **sensor-controller** (what decides). The first prototypes are bench and tumour-on-chip tools only; nothing here describes a clinical instrument.

PARAMETER	PROJECTED TARGET	RATIONALE / TEST
Tip radius	$\leq 1\ \mu\text{m}$ (polymer); $\leq 0.5\ \mu\text{m}$ (metal)	Must be well below cell diameter so a single cell, not a cluster, is engaged. SEM before and after cycling.
Needle height	100–600 μm (design sweep)	Spans spheroid depths in Phase II; taller needles buckle more easily. Euler buckling check plus phantom insertion.
Pitch	50–200 μm	Trade-off between coverage and the “bed-of-nails” effect, where dense arrays spread load and fail to penetrate.
Actuation	Piezo axial oscillation, 0.1–10 kHz, sub- μm amplitude	Oscillation lowers insertion force and gives a tunable “shred-rate” dial. Range to be narrowed experimentally.
Force resolution	$\leq 1\ \mu\text{N}$ per needle (bench rig)	Needed to map F_{50} curves (H1). Initial rig: load cell plus calibrated cantilever.
Sterilization	Survives EtO or gamma with $< 10\%$ property loss	Epoxies and chitosan can degrade under gamma irradiation; test both routes early.
Lysis-rate ceiling	Software-limited, per volume per minute	The tumour lysis syndrome (TLS) safeguard — see below.

SHRED-RATE CONTROL AND TUMOUR LYSIS SYNDROME

Killing a large tumour mass quickly releases potassium, phosphate and nucleic acids (which the body converts to uric acid) faster than the kidneys can clear them. That metabolic emergency is tumour lysis syndrome, graded clinically by the Cairo–Bishop criteria.^[12] Rev 1.0 identified the risk correctly. Rev 2.0 turns it into an engineering requirement: **the controller enforces a hard ceiling on lysed volume per unit time**, independent of the AI, with the ceiling set in Phase IV from serum potassium, phosphate and uric acid measurements.

DESIGN PRINCIPLE

The machine-learning model may *reduce* aggressiveness at any time, but it can never raise force, frequency or lysis rate above limits fixed in deterministic code and verified before each session.

06 AI IMPEDANCE SENSING & CLOSED-LOOP CONTROL

Electrical impedance gives a label-free, real-time view of cells. Electric cell-substrate impedance sensing (ECIS), pioneered by Giaever and Keese, showed that impedance resolves cell spreading and even nanometre-scale "micromotion" of living cells.^[13] Intact membranes act as capacitors; when a membrane ruptures the capacitive signature collapses. This makes impedance a natural sensor both for *finding* target cells and for *confirming* lysis.

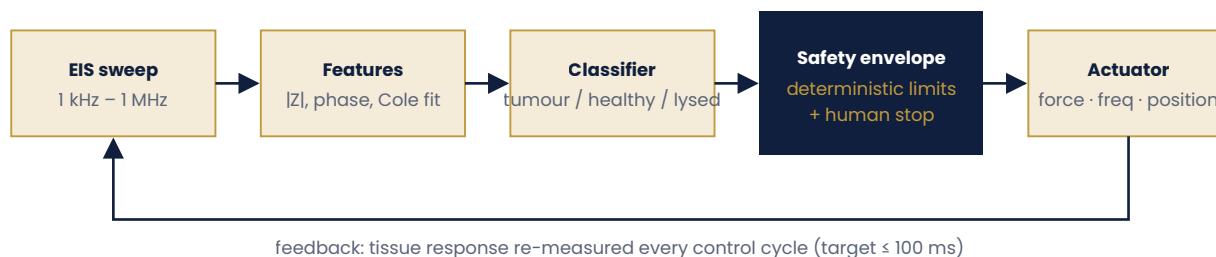


Figure 3. Closed-loop architecture. The safety envelope sits between the AI and the hardware, not beside it.

MACHINE-LEARNING PLAN

- **Start interpretable.** Begin with logistic regression and gradient-boosted trees on physically meaningful features (equivalent-circuit parameters, dispersion frequencies) before any deep model. Interpretability is evidence for reviewers and regulators.
- **Split by spheroid, not by measurement.** Readings from one spheroid are correlated; mixing them across training and test sets inflates accuracy. All metrics must use spheroid-level (and, later, animal-level) cross-validation.
- **Report what matters clinically.** Sensitivity for tumour, and above all the *false-positive rate on healthy tissue*, because a false positive here means healthy cells destroyed.
- **Calibrate and abstain.** The model outputs calibrated probabilities and may return "uncertain", which the controller treats as "do not actuate".
- **Lock and log.** Freeze model versions per experiment; log every input, output and actuation for traceability (this becomes the software-of-medical-device record later).

"Rolling-wave" control from Rev 1.0 is kept as a concept — sequential activation across the array so lysis advances as a front rather than everywhere at once — because it naturally supports the TLS rate ceiling and lets each zone be re-measured before the next is treated.

07 PHASE PLAN, TIMELINE & GO/NO-GO GATES

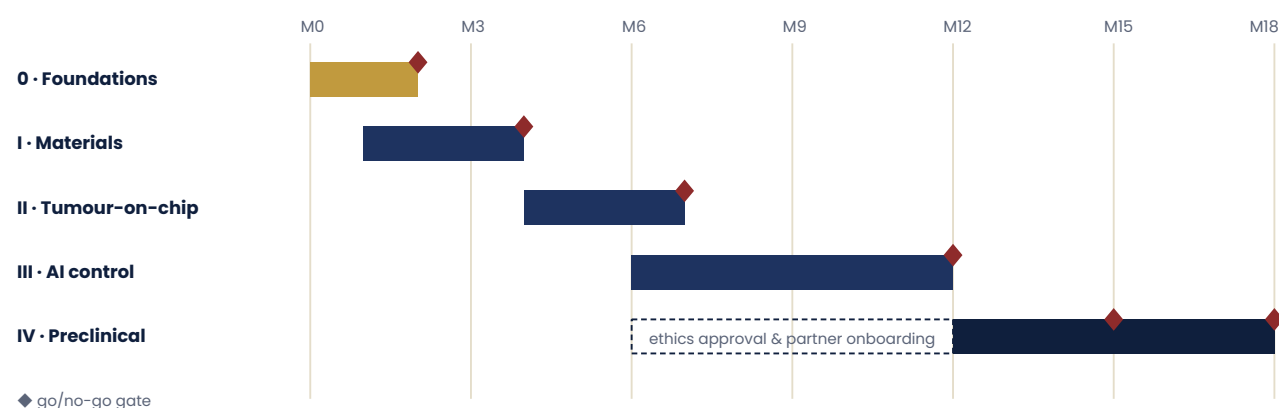


Figure 4. Projected 18-month schedule. Phase III overlaps late Phase II; Phase IV cannot begin until a certified animal-care partner has approved the protocol, which runs in parallel from Month 6.

PHASE	WORK & DELIVERABLES	GO/NO-GO GATE (PROJECTED CRITERIA)
0 • Foundations Months 0–2	Systematic literature and patent prior-art review; formulation shortlist; fabrication route selection (PDMS micromoulding vs two-photon lithography); provisional patent filing; partner outreach.	G0: provisional filed; at least one academic wet-lab partner committed; prior art leaves claimable space.
I • Materials Months 1–3	Resin and laminate tensile testing (ASTM D638 / D3039); microneedle fabrication and SEM; insertion and buckling tests in phantoms; ISO 10993-5 extract cytotoxicity; chitosan coating and debris-binding kinetics.	G1: H2 and H3 pass for at least one formulation; tip radius $\leq 1 \mu\text{m}$ reproducible across 3 batches.
II • Tumour-on-chip Months 4–6	PDMS microfluidic testbed with integrated electrodes; co-culture spheroids (tumour + fibroblast stroma); F_{50} mapping; live/dead imaging; impedance dataset collection.	G2: H1 supported (F_{50} ratio ≥ 2 in ≥ 2 of 3 cell-line pairs). <i>If not, pivot to targeted coating or drug-delivery microneedle.</i>
III • AI control Months 6–12	Feature engineering; classifier training with spheroid-level validation; safety-envelope firmware; rolling-wave controller; closed-loop on-chip demonstrations.	G3: H4 met ($\text{AUC} \geq 0.90$); closed loop spares $\geq 90\%$ of healthy-region cells while lysing $\geq 70\%$ of tumour-region cells.
IV • Preclinical Months 12–18	With a certified partner institution: subcutaneous xenograft pilot, tumour volume and survival, serum $\text{K}^+/\text{PO}_4^{3-}$ /uric acid for TLS, histopathology of tissue around the tracks.	G4 (M15): no TLS markers above threshold; local tissue damage acceptable to the veterinary pathologist. G5 (M18): efficacy signal vs sham.

TIMELINE REALISM

Eighteen months from TRL 1 to an in-vivo efficacy signal is aggressive even for a funded academic lab. Treat the dates as best-case targets. The schedule-critical path is not engineering; it is securing wet-lab and animal-facility access through partners (Section 11).

08 RISK REGISTER

RISK	LIKELY	IMPACT	MITIGATION
No selective force window exists (H1 fails)	MED	HIGH	Gate G2 decides early. Pivots: antibody or peptide-targeted tips; use the array for intratumoural drug delivery, a well-established microneedle role.
Polymer tips blunt or fracture	HIGH	MED	Metal-tipped hybrid fallback; carbon-nanosheet reinforcement; oscillatory insertion to cut force.
Cytotoxic leachables from bio-epoxy	MED	HIGH	Full-cure verification (DSC); post-cure extraction; ISO 10993-18 chemical characterization; reduce bio-content if needed.
Nanocarbon wear debris toxicity	MED	MED	Wear testing with particle collection; encapsulate nanosheets below surface layer.
Tumour lysis syndrome in vivo	LOW (small models)	HIGH	Hard lysis-rate ceiling; serum monitoring; staged rolling-wave sessions.
AI false positives on healthy tissue	MED	HIGH	Abstain-on-uncertainty; deterministic limits; optimize for specificity, not accuracy.
Mechanical seeding of tumour cells along tracks	MED	HIGH	Needle-tract seeding is a recognised concern in biopsy; histology of tracks is a mandatory Phase IV endpoint.
Loss of patent rights through early publication	HIGH	HIGH	File provisional before any Zenodo/Scribd/GitHub posting (Section 10).
No lab or animal-facility access	HIGH	HIGH	Partnership-first strategy; contract research organization as a backup for Phase I testing.

09 REGULATORY & ETHICS PATHWAY

CANADA

Medical devices are governed by the **Medical Devices Regulations (SOR/98-282)**, which sort devices into Classes I to IV by risk.^[14] An invasive device intended to destroy tissue would be expected to fall in a higher-risk class; formal classification must be confirmed with Health Canada. Any human study would need an **Investigational Testing Authorization** under the same regulations. Animal work must follow **Canadian Council on Animal Care (CCAC)** guidelines, including predefined humane and scientific endpoints for tumour models, under an institutional animal-care committee.^[15]

UNITED STATES

Histotripsy's October 2023 **De Novo** authorization is the most relevant precedent: a first-of-kind mechanical tumour-destruction device with no predicate.^[1] A Hempoxy device would likely follow a similar route, with an Investigational Device Exemption (IDE) for clinical study.

QUALITY BACKBONE (START EARLY)

Design controls and records compatible with **ISO 13485** (quality management), **ISO 14971** (risk management) and **ISO 10993-1:2025** (biological evaluation). Starting these habits in Phase I costs little and avoids re-doing work later.

10 INTELLECTUAL PROPERTY & PUBLICATION STRATEGY

CRITICAL — READ BEFORE POSTING THIS DOCUMENT

Canada allows a **12-month grace period** for an inventor's own disclosures, counted back from the *Canadian* filing date (not the priority date).^[16] The United States also has a one-year grace period but measures it differently; Europe and many other jurisdictions apply **absolute novelty**, where any prior public disclosure can bar a patent. Publishing technical detail on Zenodo, Scribd, GitHub or a blog before filing could therefore forfeit European rights outright and leave Canadian rights on a 12-month clock. CIPO consulted on its grace-period rules until 23 June 2026; check for changes before relying on them.^[16]

PATENT FAMILIES (TARGETED)

FAMILY	CLAIM FOCUS	PRIOR ART TO CLEAR
A · Hempoxy biomedical composite	Hybrid EHO/epoxy resin with hemp carbon-nanosheet reinforcement, formulated and cured for tissue-contacting microstructures.	Bio-epoxy composites; hemp carbon nanosheet patents.
B · Mechano-selective lysis arrays	Array geometries and oscillation regimes defined by a measured F_{50} selectivity window; chitosan debris capture.	Microneedle arrays; mechanobactericidal nanostructures; molecular-machine patents.
C · Impedance-guided control	Closed loop with a deterministic safety envelope, abstention and lysis-rate ceiling; rolling-wave activation.	Impedance-guided ablation (e.g., irreversible electroporation systems).

Method claims built on a selectivity window are only as strong as the data behind them; Family B is best filed as a provisional now and completed after Gate G2.

PHASED DISSEMINATION (REVISED)

WHEN	VENUE TYPE	CONTENT
Month 2	Provisional patents	Families A–C, before any public disclosure.
Month 6	Materials science journal	Hempoxy microneedle fabrication and characterization (Phase I).
Month 10	Bioengineering / lab-on-chip	Tumour-on-chip testbed and F_{50} selectivity data (Phase II).
Month 16	Biomedical AI / computing	Impedance classifier and safety-envelope controller (Phase III).
Month 22	Oncology journal	Preclinical efficacy and safety (Phase IV).

Zenodo remains valuable for datasets and preprints *after* filing; deposit with DOIs and link them to the ORCID record for traceability.

II PARTNERSHIPS & RESOURCES

As a solo, pre-revenue practice, Landry Industries' advantage is ideas, speed and cross-domain synthesis. Wet-lab, cell-culture, microfabrication and animal work require shared infrastructure, so partnership is the execution strategy rather than an add-on.

NEED	WHERE TO LOOK
Cell culture, BSL-2 lab, ISO 10993-5	Université de Moncton and University of New Brunswick labs; commercial biocompatibility CROs for formal testing.
Atlantic cancer-research network	Beatrice Hunter Cancer Research Institute (Halifax), which links cancer researchers across Atlantic Canada and runs Atlantic research grant programmes. ^[17]
Microfabrication	University cleanrooms or nanofab user facilities (fee-for-service access to SEM, lithography, two-photon printing).
Animal studies	CCAC-certified institutional facility via an academic co-investigator.
Funding	Industry–academic partnership programmes (e.g., Mitacs internships, NRC IRAP advisory support, NSERC Alliance via a university partner) — confirm current eligibility and calls before applying.

NEXT THREE ACTIONS

1. Commission a professional prior-art search and file provisional patents for Families A–C.
2. Approach one materials lab and one cancer-biology lab with a two-page, non-confidential summary (post-filing).
3. Run the cheapest decisive experiment: fabricate one Hempoxy formulation and run ISO 10993-5 extract cytotoxicity (H3). If it fails, everything downstream changes.

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DOCUMENT STATUS & RESPONSIBLE-USE STATEMENT

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