



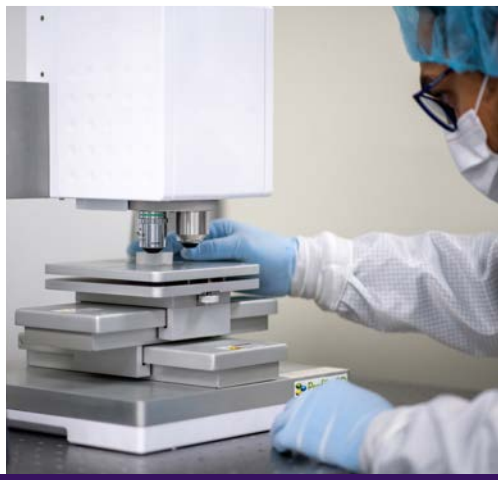

PROJECT UPDATE:

Axolotl Biosciences BrainPrint Microsphere Generator

PROVIDING HIGH-QUALITY REAGENTS FOR 3D PRINTING HUMAN TISSUE MODELS

Axolotl Biosciences is a privately owned company that spun-off of a bio-printing-focused research group led by Dr. Stephanie Willerth at the University of Victoria.

3D bioprinting enables the creation of functional human tissues on demand, and it is suitable for various applications in repairing the human body as well as orthogonal applications such as drug screening. Axolotl's BrainPrint microsphere generator is a commercial scale and high-throughput microfluidic production system for drug-releasing microspheres necessary to produce bioink for 3D tissue bioprinting.

Two novel Axolotl Biosciences bioink formulations (TissuePrint and BrainPrint) generate reproducible and functional human tissues derived from stem cells. BrainPrint contains drug-encapsulated microspheres, maintains high levels of cellular viability post-printing, and promote cellular differentiation into stable, mature neural tissues similar to those found in the brain. They are cheaper and require less labour than traditional tissue engineering and other commercially available bioinks.

THE CHALLENGE

Scaling up production of the drug-releasing microspheres while maintaining the required size and drug encapsulation efficiency of the microspheres needed microfluidics commercialization expertise. Major challenges for transfer to manufacturing were finding a chemically compatible material for the device and a suitable manufacturing technique.

THE PROCESS

With funding support from Next Generation Manufacturing Canada (NGen), Axolotl engaged StarFish Medical to implement high-throughput microfluidic processes for fabricating these drug-releasing microspheres based on prototypes developed in the Willerth and Elvira labs at the University of Victoria. The process included:

- Design prototype microfluidic cartridge using analytical and numerical analysis and computational fluid dynamics simulations of droplet generation parameters to reduce physical prototyping development costs. Check out simulation in 2D and 3D.
- Prototype microfluidic cartridges in-house for the proof of concept.
- Design manufacturing process to ensure microfluidic cartridges are optimized for scale-up and produce microspheres that meet defined specifications.
- Support Axolotl development and implementation of quality control processes for the novel BrainPrint bioink and beta testing to ensure viability as a trusted commercial product.
- Support regulatory submission activities.

Beta testing and evaluation of BrainPrint bioink are coordinated by Axolotl working closely with StarFish Medical to adapt the preliminary device prototype into a design suitable for manufacturing larger quantities of the drug-releasing microspheres for commercial use.

In-house prototypes were designed by StarFish Medical using the SolidWorks platform and manufactured at StarFish Medical using a high-precision Computer Numerical Control (CNC) machine (MDA precision), and a BossLaser laser cutter for assembly.

Axolotl verified the prototypes and StarFish Medical developed high-level manufacturing transfer plans taking into consideration all risk factors associated with the manufacturing.

Designs were presented to microfluidics manufacturers and divided into categories based on low- and high-volume production then evaluated according to the manufacturing techniques and materials used by each manufacturer. This approach informed the supply chain management and resulted in timely resourcing.

RESULTS

- Two microfluidic concepts and prototypes that can produce drug-releasing microspheres with the desired output volume and microsphere specifications.
- Novel technique to seal aluminum and Peek microfluidic cartridges while maintaining optical transparency.
- Design transfer to manufacturing.

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PHONE: (250) 388-3537 | TOLL FREE: 1 (877) 822-3537
info@starfishmedical.com

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