Optimizing Delivery System Testing: An Analysis of Outsourcing vs. In-House Testing and Fluid Path Considerations

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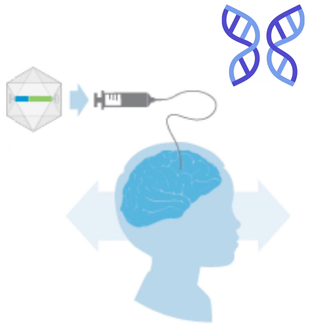
1. Background

Dravet Syndrome: Mutated *SCN1A* gene; reduced neuron Na+ channels

- ➢ Seizures, neurodevelopmental impact, mortality
- ➢ 1:15,500 affected

ETX101: AAV9 capsid for gene upregulation to increase Na+ channels



2. Introduction

Problem
- ➢ Comparing programs for internal and external testing for 510(k)
- ➢ Understanding drug waste of delivery system

Goal
- ➢ Choose the best design program
- ➢ Analyze medication and buffer flows

Limitations
- ➢ Finite lab space
- ➢ Cost
- ➢ Vivarium requirements

Deliverables
- ➢ Testing requirements of delivery systems
- ➢ Internal and external program costs
- ➢ Make vs. Buy enablement plan
- ➢ Drug fluid dynamics analysis

3. Biocompatibility

Demonstrates the safety, efficacy, and compatibility of the device in contact with the human body for FDA approval

- ➢ (T1) Cytotoxicity
- ➢ (T2) Sensitization
- ➢ (T3) Irritation
- ➢ (T4) Systemic Toxicity
- ➢ (T5) Pyrogenicity

4. Outsourcing Tests

Test	Lab A Cost	Lab B Cost
T1	$785	$585
T2	$13,520	$15,750
T3	$2,710	$3,750
T4	$1,840	$3,975
T5	$1,235	$3,950
Additional Tests	$9,100	-
Total	**$29,200**	**$28,000**

5. Insourcing Tests

T1	$4,200/test
T2-T5*	$1,400/test
New Equipment*	$16,000
Program Total*	**$26,000**

*Does not include vivarium costs

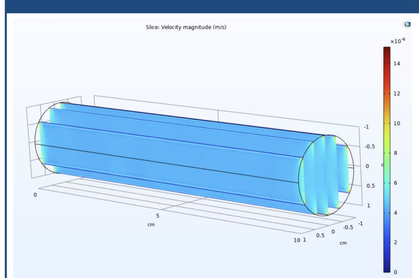
6. Make versus Buy Assessment

	Encoded Therapeutics	Lab A	Lab B
Cost	1	4	3
Lead Time	4	2	3
Assurance of Supply	2	4	3
Quality	3	4	4
Customer Satisfaction	4	4	2
Total	**14**	**18**	**15**

- ➢ Cost - cost of program
- ➢ Lead Time - results delivery time
- ➢ Assurance of Supply - capacity and continuity
- ➢ Quality - GMP and certifications
- ➢ Customer Satisfaction - interactions and experience

Score	Definition
1	Cannot meet expectations
2	Potential risks to meet expectations
3	Able to meet expectations
4	Supports current and future expectations

7. Fluid Dynamics



- ➢ Dr. Stefano Menegatti assisted with fluid flow calculations
- ➢ Laminar flow (Re<2000)
- ➢ Buffer and Medication properties: Water
- ➢ No medication left in device

COMSOL Software
Re ≈ 16 to 32

* A more detailed simulation would have been completed given more time

8. Conclusion

- ➢ Insourcing tests results in a more expensive approach
- ➢ Lab A was more suitable than Lab B
- ➢ Laminar flow through catheter without unintended mixing
  - ○ No medication wastage (Buffer still necessary)

9. Acknowledgements

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