

OBJECTIVE

- Enhance the cell manufacturing innovation ecosystem
- Identify opportunity areas where small and medium enterprises could capitalize on and develop innovations on the CMaT industry
- Evaluate commercialization models for fast and efficient implementation

METHODOLOGY

- Exploratory research utilizing secondary sources to perform market analysis
- A PESTEL analysis was implemented to look into factors that could favor or hinder CMaT industry



- Interviews were conducted to stakeholders within the pharmaceutical and biotechnology industry in Puerto Rico
- Commercialization models were assessed to find a fast lab to market implementation of such technologies

RESULTS

OPPORTUNITIES:

- **Political:**
 - Act 60-2019: Puerto Rico's new Incentive Code
 - Law 62 support for small and medium enterprises
- **Economic:**
 - The pharmaceutical industry has been established in PR for more than 60 years
 - Puerto Rico produces 8 of the top 15 most sold biopharmaceuticals in the world
- **Social:**
 - Pharmaceutical companies have more than 13k employees prepared in the STEM fields
 - The island's start up culture has grown exponentially
- **Technological:**
 - 50 pharmaceutical, biotechnology, and medical devices companies are already established in the island
 - Puerto Rico has 46 FDA approved manufacturing sites with 12 of the top 20 pharmaceutical companies
- **Environmental:**
 - The strategic location of the island makes it an essential port
- **Legal:**
 - Puerto Rico is a US territory hence federal regulations apply

LIMITATIONS:

- **Political:**
 - Insufficient medicaid funds
- **Economic:**
 - 70 billion USD bond obligations and high debt
 - Removal of section 936 of the federal tax code
 - Estimated impact of Hurricane Maria on the island's economy was 43 billion USD
- **Social:**
 - High poverty and unemployment levels
 - Medical professionals' migration along with impacted health care access
 - Brain drain previous to Hurricane Maria
- **Technological:**
 - High cost of utilities and manufacturing
 - Humanitarian crisis after Hurricane Maria
- **Environmental:**
 - Location makes it prone to hurricanes
 - COVID-19 lockdown impacts
- **Legal:**
 - Food and Drug Administration's process of approval is extensive and costly

CONCLUSIONS

PESTEL framework provided insights on the macroenvironment of the cell manufacturing therapy market and identified opportunities and limitations for its growth

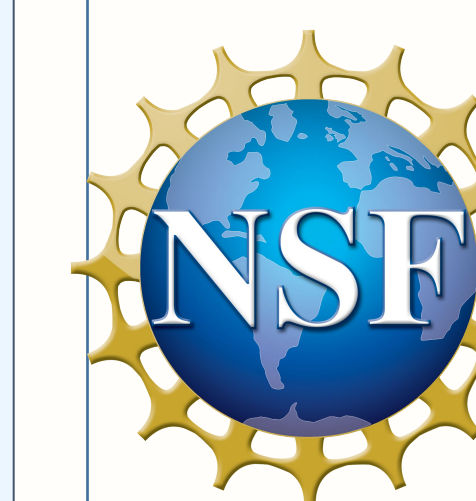
Conditions are currently favorable to develop the cell manufacturing therapy industry in Puerto Rico and the United States

Allen and Lean model were estimated to be suitable for the biotechnology and pharmaceutical industry implementation

FUTURE WORK

Future research is needed to capitalize on and develop innovations by analyzing the cell manufacturing industry in the US and PR. Additionally, more information is necessary to find commercialization opportunities from cell manufacturing technologies inventions/innovations.

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REFERENCES

