How Feasible is the $1 Lab-on-a-Chip System?

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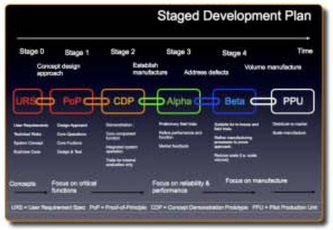
INTRODUCTION

Successful technology transfer from laboratory prototype to full-scale manufacture of medical diagnostic products is a matter of managing complexity. While many will recognise the need to reduce health care costs as a key driver for scientific and technological innovation, the often-quoted goal of achieving a $1 consumable device relies upon a complex set of solutions to scientific, design, manufacturing and regulatory requirements. It is often considered that simply increasing the scale of production will reduce component costs, however when trying to introduce new technologies to the market it is equally important to make the business work when only low or intermediate volumes of consumables are required by the market. In other words the company must make money no matter what scale the manufactured volume.

These realities about commercialisation of lab-on-a-chip systems mean that product development strategies need not only to address the technical development phases but create useful cost models to guide design, development and investment decisions.

STAGED DEVELOPMENT PLAN



DESIGN FOR MANUFACTURE

A Staged Development Plan manages technical and financial risks. The development process is tailored to meet the regulatory requirements for the product i.e. CFR820, CE, ISO13485 and others.

Stage 0 importantly establishes the User Requirements Specification and identifies key technical risks to be addressed in the development program.

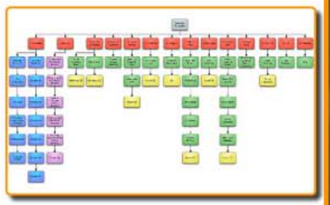
Stage 1 demonstrates each of the high risk technical items as individual sub-functions in Proof-of-Principle e.g. valving, pumping, fluidic mixing, metering, detection sensitivity, reagent stability etc.

Stage 2 brings each of the functional elements together and demonstrates that the system performs to spec. The end of Stage 2 is **DESIGN FREEZE**. All subsequent work is on manufacturing issues. Any change to design must be under strict design control protocols.

Stage 3 uses a combination of manual and semi-automated production techniques to make the first 100's to low 1,000's of ALPHA cartridges. Tests ensure that the manufacturing variations are understood

Stage 4 typically produces low 10,000's of cards for clinical trials. Production should be as near as possible equivalent to anticipated volume production.

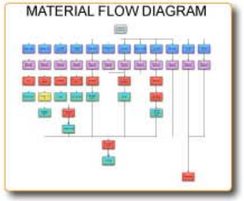
MANUFACTURING PLANNING



PLANNING DIAGRAMS

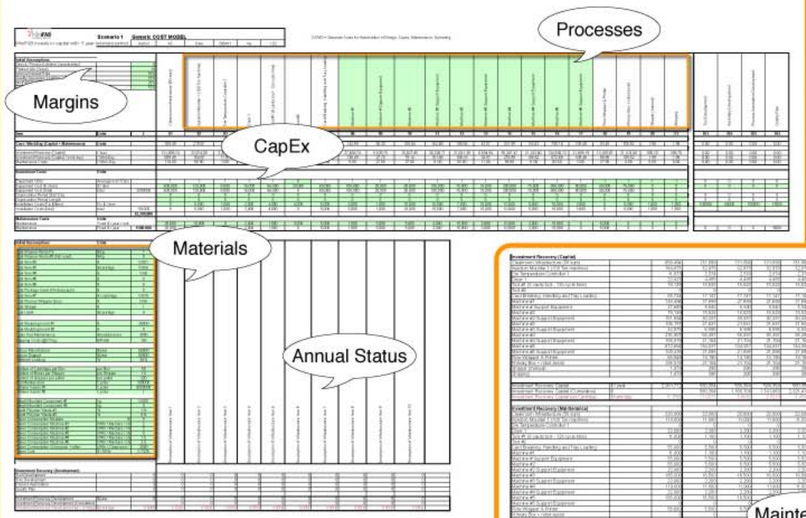
The Manufacturing Plan captures materials and processing steps to be implemented. Quality Control checks are added.

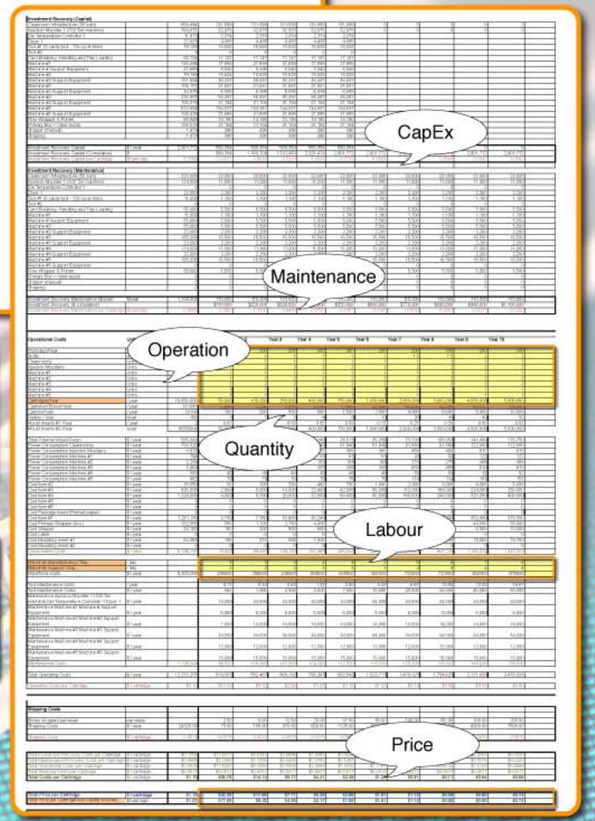
The Material Flow Diagram shows the sequence of operations, including shipping from component suppliers, required to assemble the completed Lab-on-a-chip.

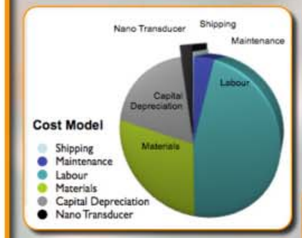


Both diagrams are used to fill in the details for the Manufacturing Cost Model and inform design decisions such as on-board / off-board reagents, use of RFID tags, integration and assembly strategy, component subcontracting, packaging, degree of manufacturing automation and CapEx financing options.

MANUFACTURING COST MODEL

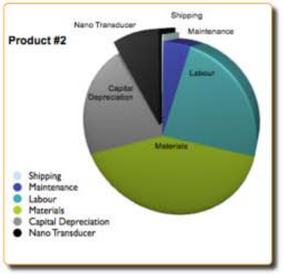






RESULTS - Cartridge Costs

Example Conditions:
- CapEx is $2.7M and is leveraged off existing infrastructure.
- CapEx depreciation over 5 years.
- Single shift operation (can model for split or multiple shifts)
- Quality overhead is 15% of operational costs



Annual Production	CapEx Amortised	No CapEx
0.1 M	$25.06	$16.71
0.4 M	$6.57	$4.49
1.0 M	$2.88	$2.04
2.0 M	$1.65	$1.23
3.0 M	$1.24	$0.96
5.0 M	$0.91	$0.74

• Labour 17% - 45% • Materials 30% - 40% • CapEx 15% - 18% • Maintenance 6% - 9%

CONCLUSION

- To gain an accurate prediction of cartridge cost it is important to start with a clear Requirements Specification - Stage 0 in the development plan.
- Plan the manufacturing and materials process flow - just one additional material makes a big difference to costs (e.g. RFID can add 30% to cost).
- Build the cost model to handle design variables as well as CapEx and investment issues - use this to create scenarios that model costs against operational choices (e.g. degree of automation).
- If capital costs are amortised against production volumes then these volumes are the most critical factors for achieving low cartridge costs.
- The nano-transducer is usually a very small part of overall cartridge costs.
- Roughly ¼ cartridge costs are capital depreciation and ¼ are labour costs.