Systems Engineering on the ChemDx Project

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What is ChemDx?

Goal: Develop a platform for an ultra-portable, low-complexity, in-vitro diagnostics system to provide indication of CWA exposure on the battlefield.

- Hand-held
- Near real-time (<5 min)
- FDA-approved medical device

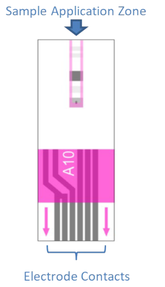
System Components:

- Meter
- Test Strip
- Controls (see below)
- Accessories

System Operation: Blood drop on a Test Strip generates an enzymatic reaction with electrical output proportional to acetylcholinesterase (AChE) activity and hemoglobin (Hgb). AChE and Hgb values can be used together to determine AChE inhibition.

Two Types of Controls:

- Check Strip: Specially-designed test strip with resistors to match electrical load and verify meter electronics.
- Control Solutions: Liquid drops applied directly to the Test Strip.
  - High; normal AChE (uninhibited)
  - Low; depressed AChE (inhibited)

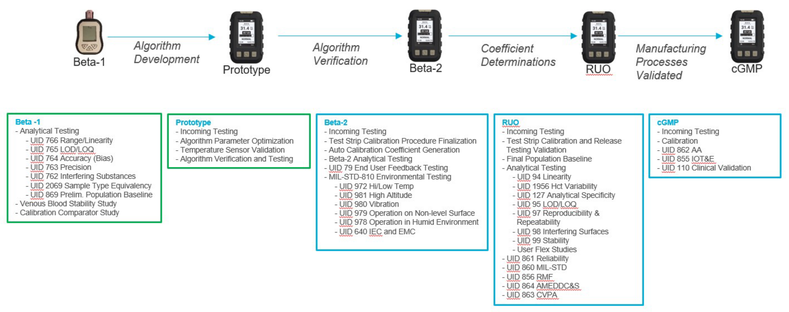


Test Strip

ChemDx Meter

Check Strip *Test Strip* *Control Solution*

Device Development Process



Systems Engineering Functions

What does the Systems Engineer do?

- Understands and coordinates the subcontractor's device development processes.
- Acts as the primary interface between the MRIGlobal team, the customer team, and the device development subcontractors.
- Helps guide the subcontractors through design needs, including:
  - Customer reviews and working groups.
  - Balancing design parameters between mechanical, electrical, and software teams.
  - Interpreting the design requirements.
  - Verification testing.
  - Handing off prototypes to the other team members at the appropriate times.

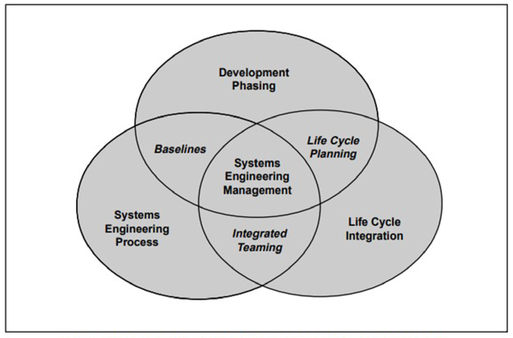


Figure 1-1. Three Activities of Systems Engineering Management

System Engineering Examples: Example 1 – Requirements Generation and Management

2	Environmental Requirements						
2.1	The ChemDx system shall be ruggedized and compatible for operation in adverse environments such as a battlefield.	Device	2.1.1	The device shall operate in temperatures ranging from 4-50°C (MIL-STD-810H 501.5 Procedure II – Operation).	The device shall operate in temperatures ranging from 10-40°C (MIL-STD-810H 501.5 Procedure II – Operation).	Essential	
		Device	2.1.2	The device shall operate in environments with relative humidity ranging from 0-95% (MIL-STD-810H 507.5 Natural Method).	The device shall operate in environments with relative humidity ranging from 0-70% (MIL-STD-810H 507.5 Natural Method).	Essential	
		Device	2.1.3	The device shall be functional after being exposed to an altitude up to 40,000 ft. (12,192 m).	The device shall be functional after being exposed to an altitude up to 15,000 ft. (4,572 m).	Fundamental	This is for transport robustness in an unpressurized air cargo transport
		Device	2.1.4	The device shall be operational at a maximum altitude of 15,000 ft.	same as target	Essential	
		Device	2.1.5	The device shall operate following exposure to vibration in military ground and air transport vehicles in the carrying case (MIL-STD-810H 514.8, 516.8).	same as target	Essential	

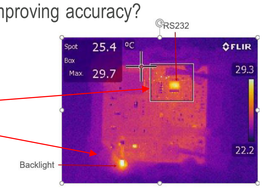
No customer-generated requirements documents other than the RFP:

- Vague, high-level functional and physical requirements (e.g. upper limits for size, weight).
- MRIGlobal works with USG customer to approve and update the Design Input Requirements (DIR).
- Subcontractor uses the DIR to guide the design team (ME, EE, SW engineers).

Systems Engineering Examples: Example 2 – Coordinated Design and Customer Teams for Temp. Sensor Redesign

Internal Sensor vs. External Sensor for measuring ambient temperature?

- Temperature measurement error introduces overall error (Test Strip reaction rate varies with temperature).
- How much error is too much? What are the design trade-offs for improving accuracy?
- Internal Sensor:
  - Well-protected, but acclimates slowly.
  - Vulnerable to heat buildup from electronics.
  - Likely will fail to get FDA approval due to errors.
- External Sensor:
  - Ruggedness concerns (drop, shock, vibration, water ingress, ESD).
  - Needs additional time to redesign circuit boards, software.
  - Higher manufacturing costs.



*Identified main heat sources: RS232 and Backlight

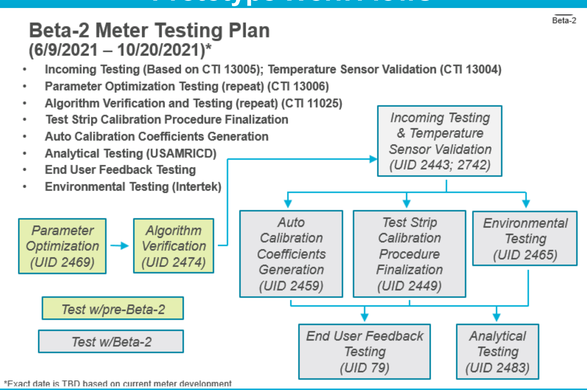
Internal Sensor: Early Design Failure

VS

External Sensor: Current Design Underway

Poor evaluation of design in early stages led to significant delays, increased costs, and project team frustrations.

Systems Engineering Examples: Example 3 – Coordinate Prototype Work Flows



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