

# HARNESSING EXPERIENCE FOR EFFICIENT MEDICAL DEVICE DEVELOPMENT

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## Factors involved in new product development success

References	New Product Development Metric
[1] A. Donnellon, "Crossfunctional teams in product development: Accommodating the structure to the process" Journal of Product Innovation Management, Sept. 2003	Cross functional team communication
[2] K. Ashihara, et.al., "Application of quality function deployment for new business R&D strategy development", ASME IMECE, Nov. 2005	Utilization of quality function deployment to identify product requirements
[3] M. Chiesa, et. al., "Measuring performance in new product development projects: A case study in the aerospace industry", Project Management Journal, Dec. 2007	Performance measurement during new product development
[4] S. Salomo, et.al., "NPD planning activities and innovation performance: The mediating role of process management and the moderating effect of product innovativeness", Journal of Product Innovation Management, July 2007	Measured the effects of project planning on NPD success
[5] A. Brown, et.al., "A survey of success factors in new product development in the medical devices industry", IEEE IEMC, June 2008	Measured NPD factors and correlated with success.

## New medical device product development factors and their correlation with success [5]

Correlation with success			
	More Successful	Less Successful	All Successful
Complexity - technical challenge	0.29	0.30	0.35
End user – customer involvement	0.27	0.21	0.31
Financial analysis used throughout development	0.27	0.36	0.34
NPD dissemination among staff	0.39	0.46	0.32

### Actual Project Data From a Single Development Company over Time

Clinical Application	Design Initiation	Time to Market (Years)	Design Complexity	New Clinical Application	New Technology
Cardiovascular	1997	5	High	No	Yes
Blood Analysis	1998	2.5	Medium	No	No
Cardiovascular	2000	3	Medium	Yes	No
Drug Delivery	2001	4	High	No	No
Cardiovascular	2002	5	High	No	Yes
Blood Analysis	2003	2	Medium	No	No
Cardiovascular	2004	4	High	No	Yes
Cardiovascular	2006	1.5	High	No	No
Arterial	2007	1	Medium	Yes	No
Wound care	2007	1.5	Low	Yes	Yes

### Medical Device Projects

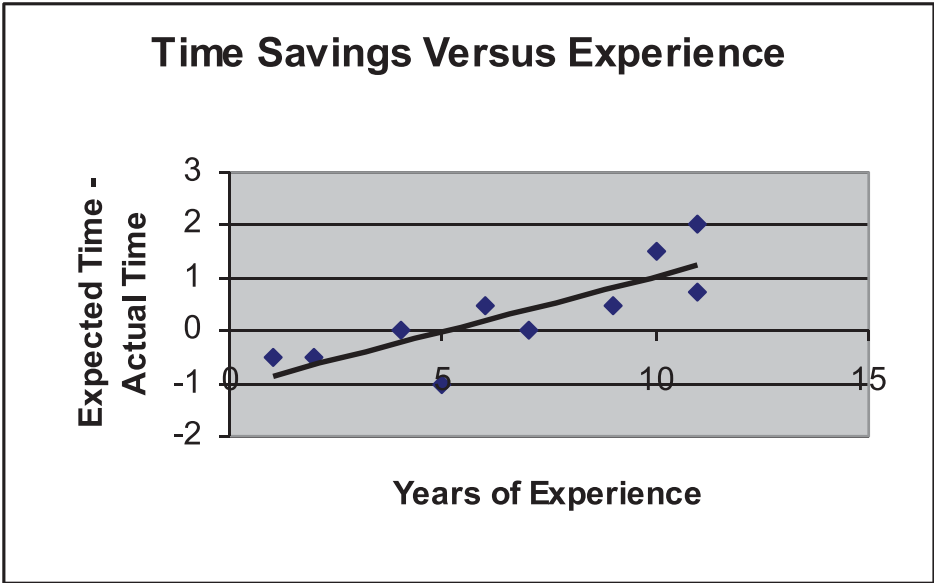
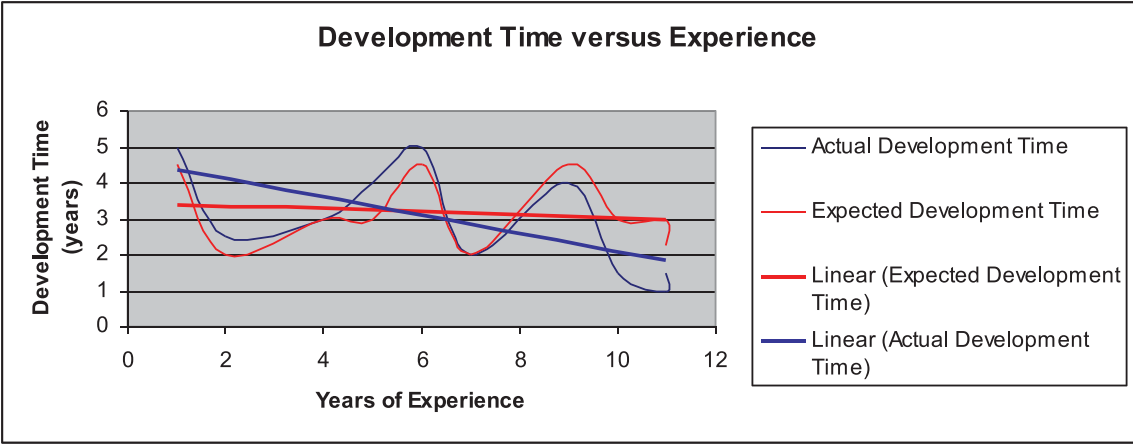
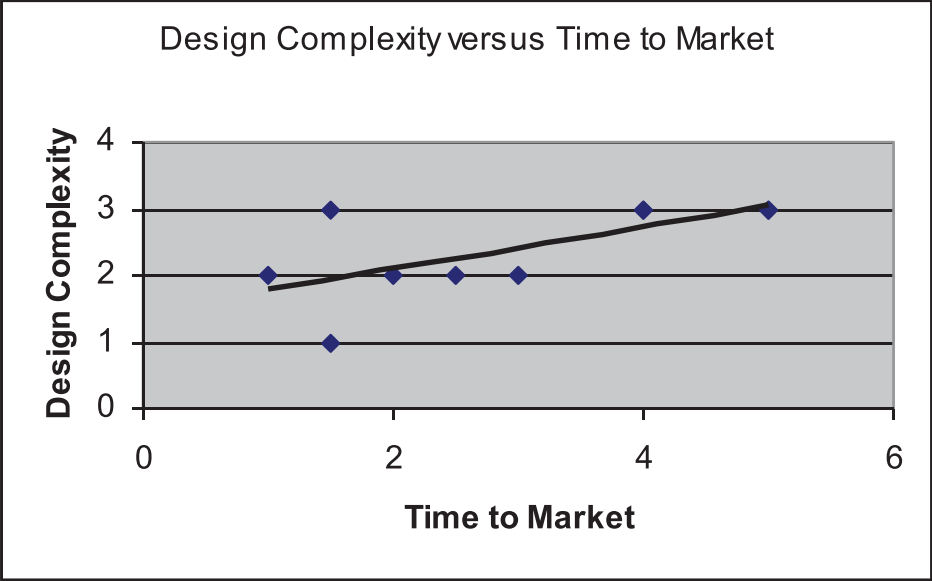
- Electromechanical devices
- Embedded software
- External devices
- All successfully released to production



Years of Experience	Design Complexity	New Clinical Application	New Technology	Actual Time to Market	Expected Development Time	Expected Time - Actual Time
1	3	1	1.5	5	4.5	-0.5
2	2	1	1	2.5	2	-0.5
4	2	1.5	1	3	3	0
5	3	1	1	4	3	-1
6	3	1	1.5	5	4.5	0.5
7	2	1	1	2	2	0
9	3	1	1.5	4	4.5	0.5
10	3	1	1	1.5	3	1.5
11	2	1.5	1	1	3	2
11	1	1.5	1.5	1.5	2.25	0.75

Calculating expected medical device development time

Expected time = Design complexity \* New application \* New technology

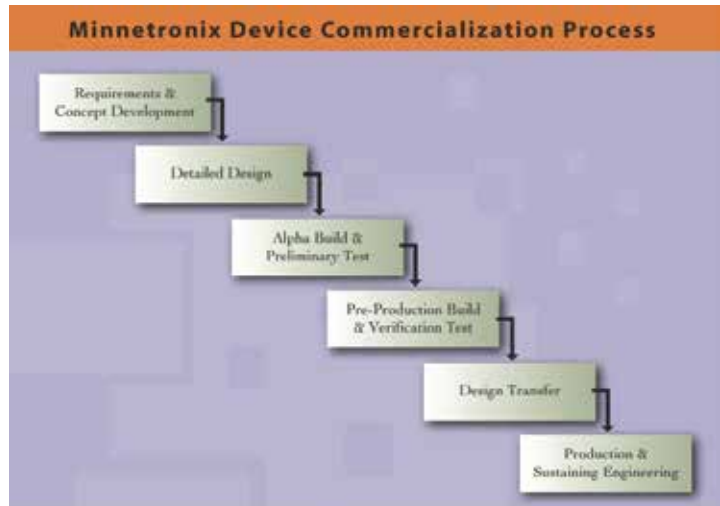


Correlation between time savings and experience = 0.82

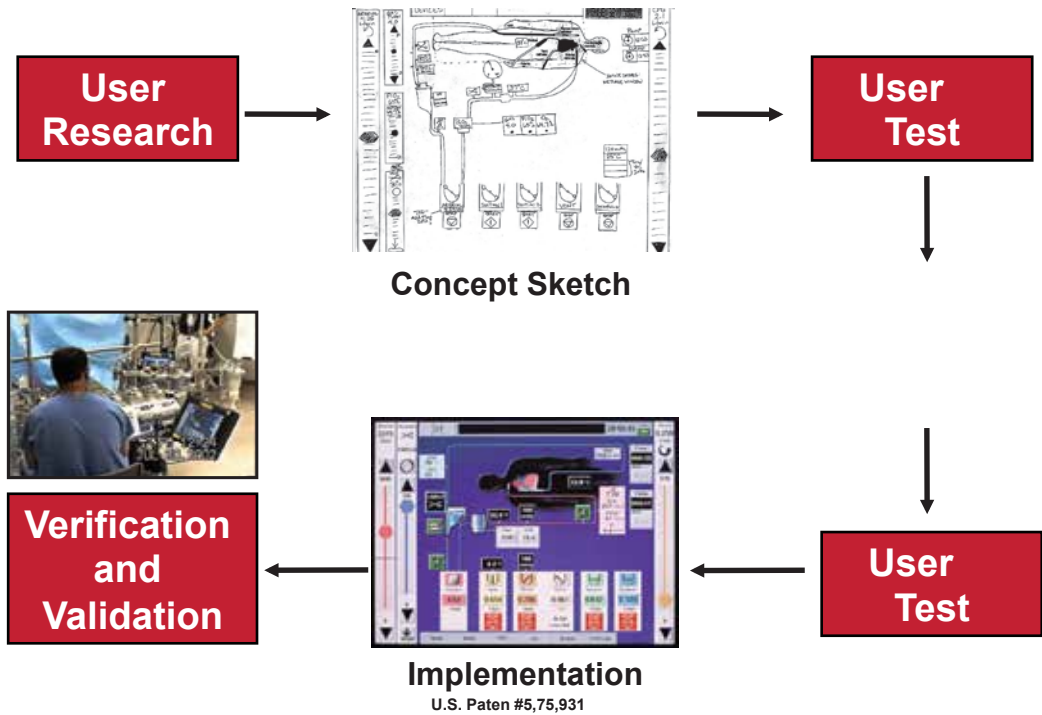
**Experience in processes => Successful program managers and Continuous process improvement**

**Processes**

1. Project planning and tracking
2. Requirements management
3. Configuration Management
4. Risk Analysis
5. Design for manufacturability
6. Design for test
7. Regulatory testing
8. Regulatory submission support



**User Interface Development**

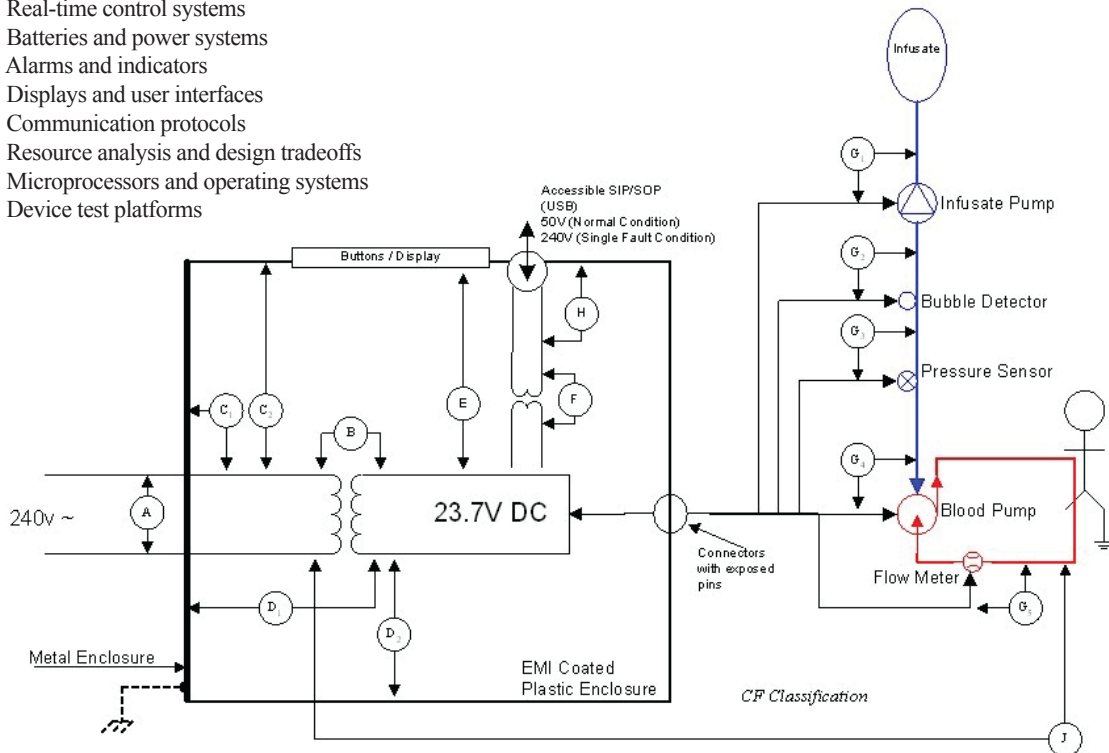


**Experience in design => Medical Device Design Experts**

1. Systems engineering
2. Electromagnetic compatibility experts
3. Manufacturability
4. Usability
5. Electronics, mechanical, software

## Experience in technology => Design frameworks for medical devices

1. Blood and fluid pumps
2. Physiological sensor interfaces
3. Real-time control systems
4. Batteries and power systems
5. Alarms and indicators
6. Displays and user interfaces
7. Communication protocols
8. Resource analysis and design tradeoffs
9. Microprocessors and operating systems
10. Device test platforms



## Experience plays a critical role in development times

### Future Work

1. When do you hit the limit for experience versus time savings
2. Can experience be applied to identifying successful projects at inception
3. How do we transfer experience



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