



Product Development: Meeting Needs Beyond the Checklist

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Fresenius Medical Care

Agenda



The Development Process

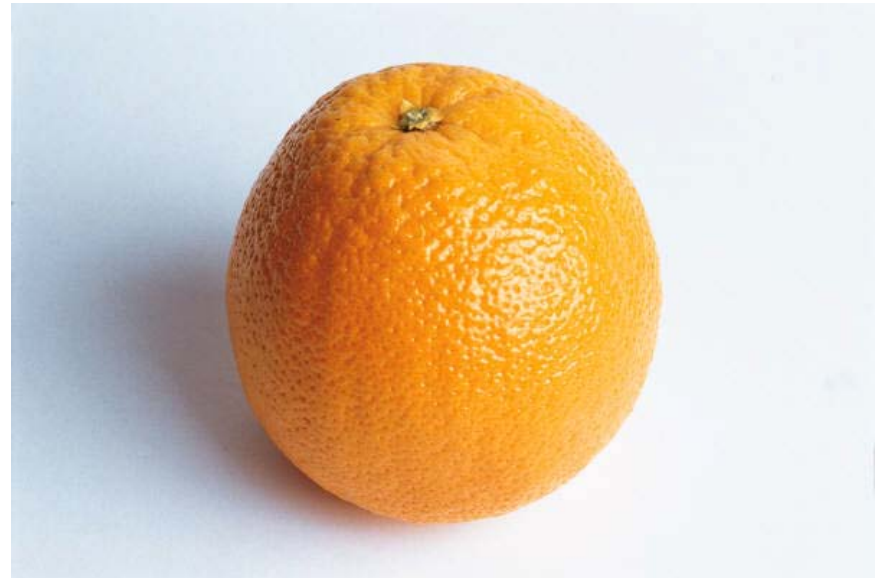
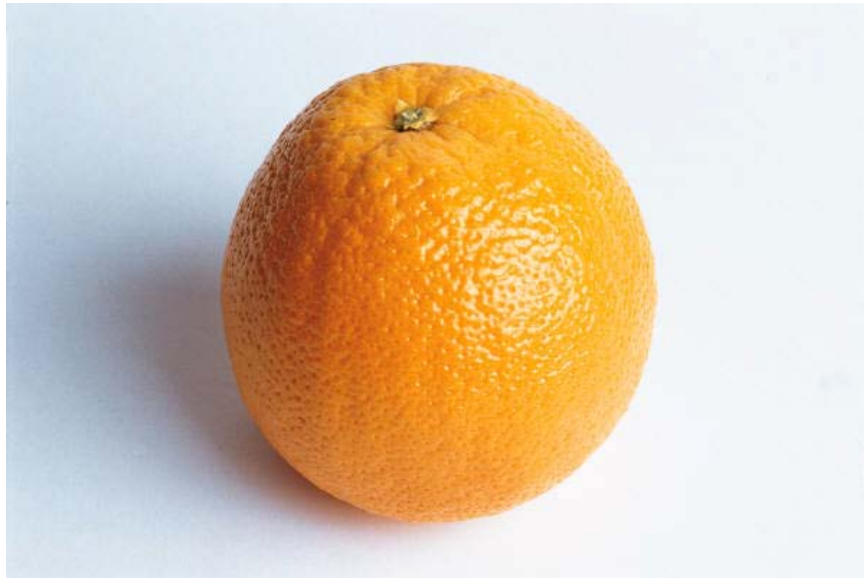
History of Technology

History of Dialysis Technology

Future of Dialysis Technology

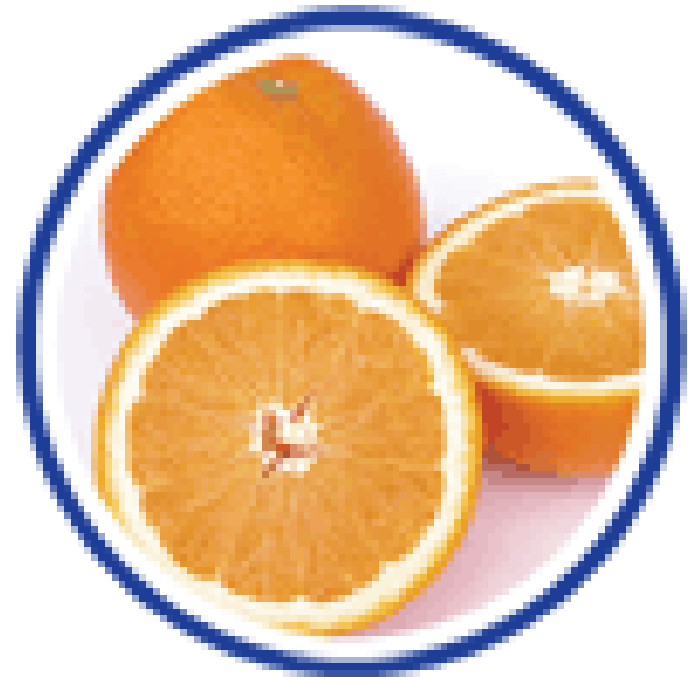
What does the Development Process Mean and Why is it needed?

Can you tell which Orange is Bad?



What does the Development Process Mean and Why is it needed?

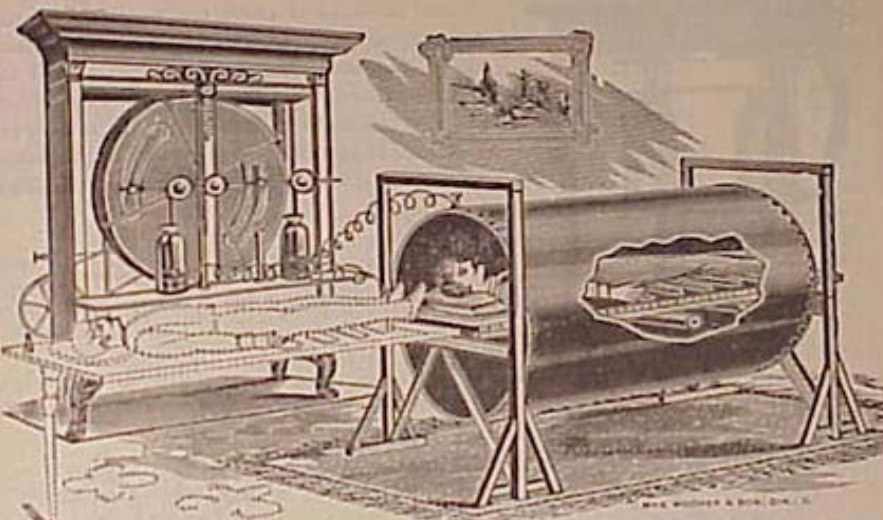
Can you now?





**COCAINE
TOOTHACHE DROPS**
Instantaneous Cure!
PRICE 15 CENTS.
Prepared by the
LLOYD MANUFACTURING CO.
218 HUDSON AVE., ALBANY, N. Y.
For sale by all Druggists.
(Registered March 1885.) See other side.

HIGH-FREQUENCY APPARATUS.
9454 THE BODY (LARGE) DIASOLENIC OR STATIC SOLENOID,
As used by Dr. Otto Jurtiner, in Cincinnati Post-Graduate School.




Ripley BELIEVE IT OR NOT - PROVES IT
THROAT DOCTORS pick OLD GOLD
in PUBLIC TEST
of A leading Cigarette



OLD GOLD
NOT A COUGH IN A CARLOAD

Dr. Williams' Pink Pills
for Pale People.



The Genuine as
Advertised, bearing
the full Name
Dr. Williams' Pink Pills for Pale People
on each Package.
Sold Within.
Accept no Substitute





<http://homedialysis.org/home-dialysis-basics/machines-and-supplies/dialysis-museum>

History of Medical Device Development

The FDA



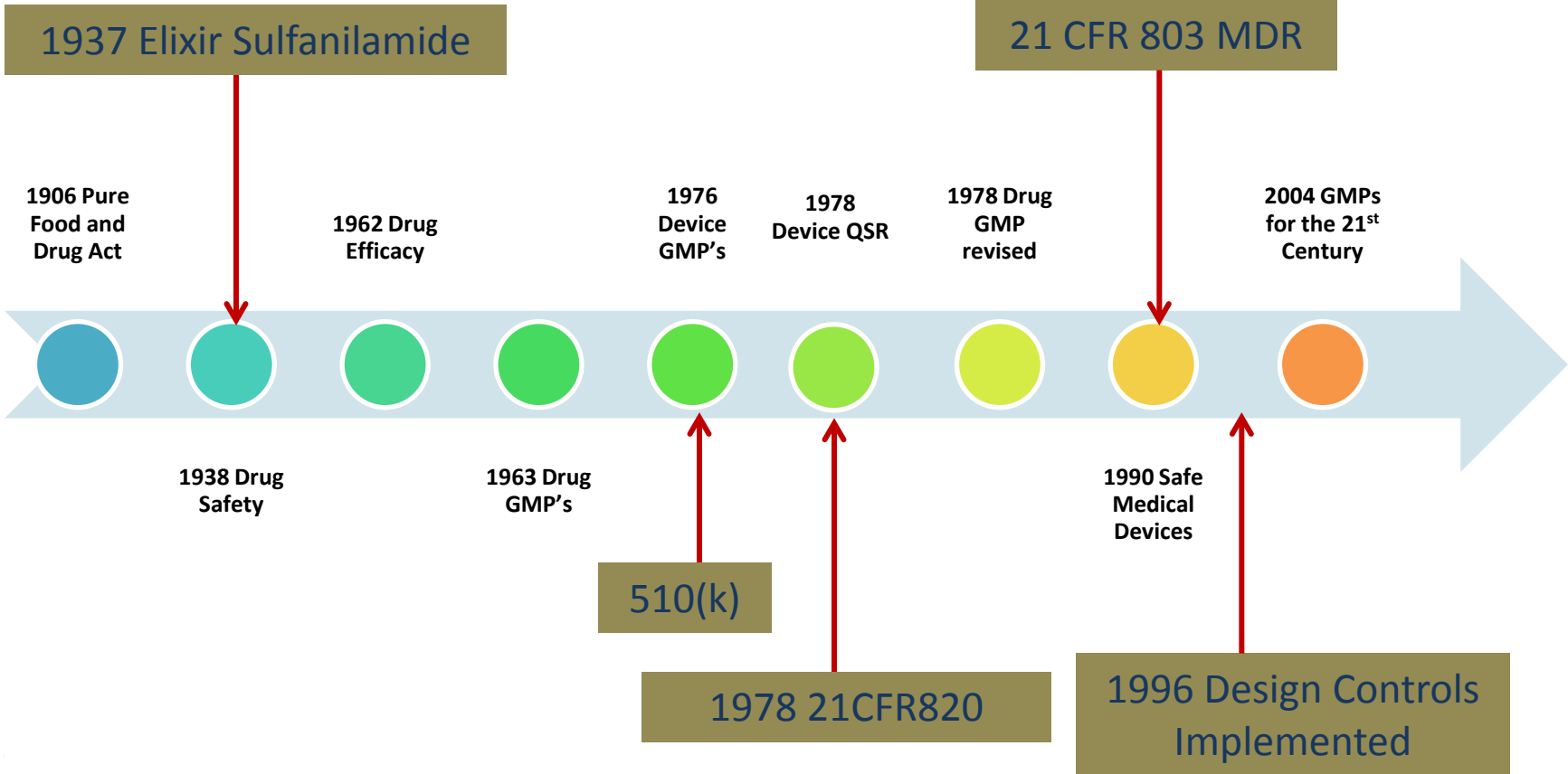
Why is the FDA important to EVERYONE?



. . . protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, medical devices, most of our nation's food supply, all cosmetics, dietary supplements, and products that give off radiation

FDA.gov

Evolution of FDA Regulations



Design Control Quality System

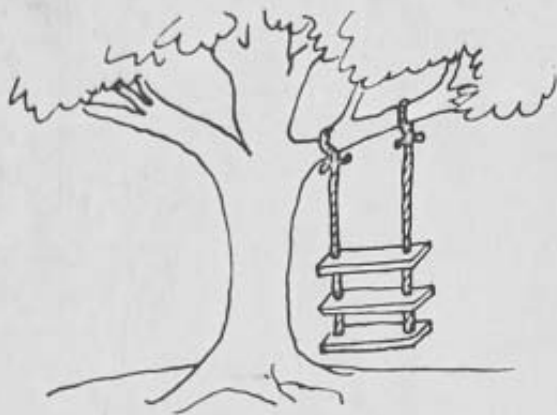
21CFR 820.30

What is Design Control? Design Control ensures systematic assessment of design increasing the likelihood that the design transferred to production will translate into a device appropriate for its intended use

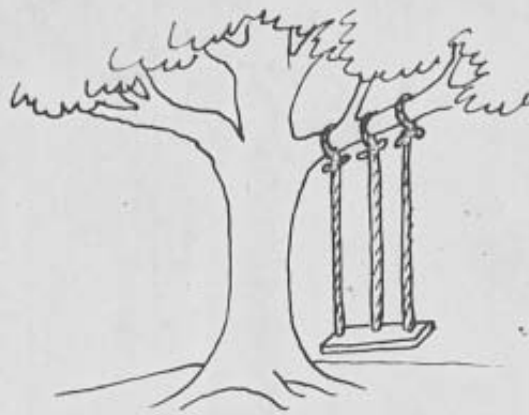
Elements of Design Control:

1. Design and Development Planning
2. Design Input
3. Design Output
4. Design Review
5. Design Verification
6. Design Validation
7. Design Transfer
8. Design Changes
9. Design History File

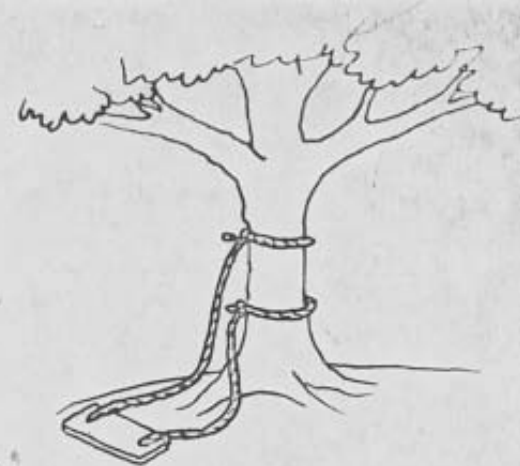




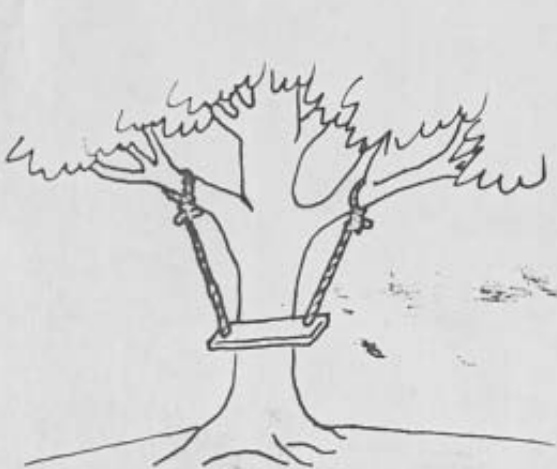
AS MARKETING REQUESTED IT



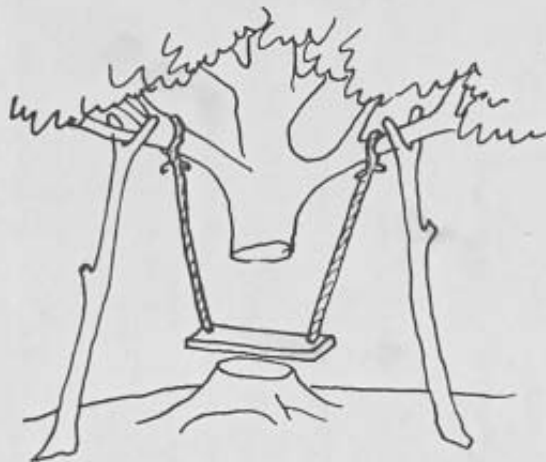
AS SALES ORDERED IT



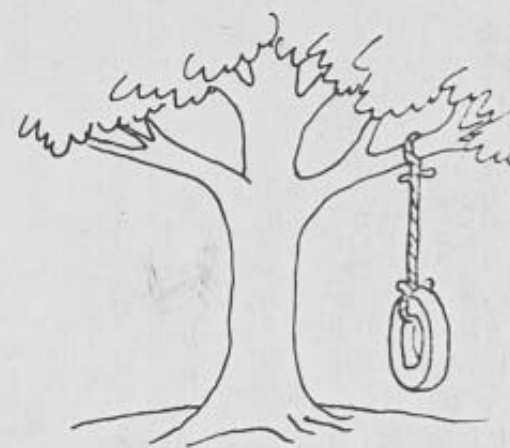
AS ENGINEERING DESIGNED IT



AS WE MANUFACTURED IT



AS FIELD SERVICE INSTALLED IT

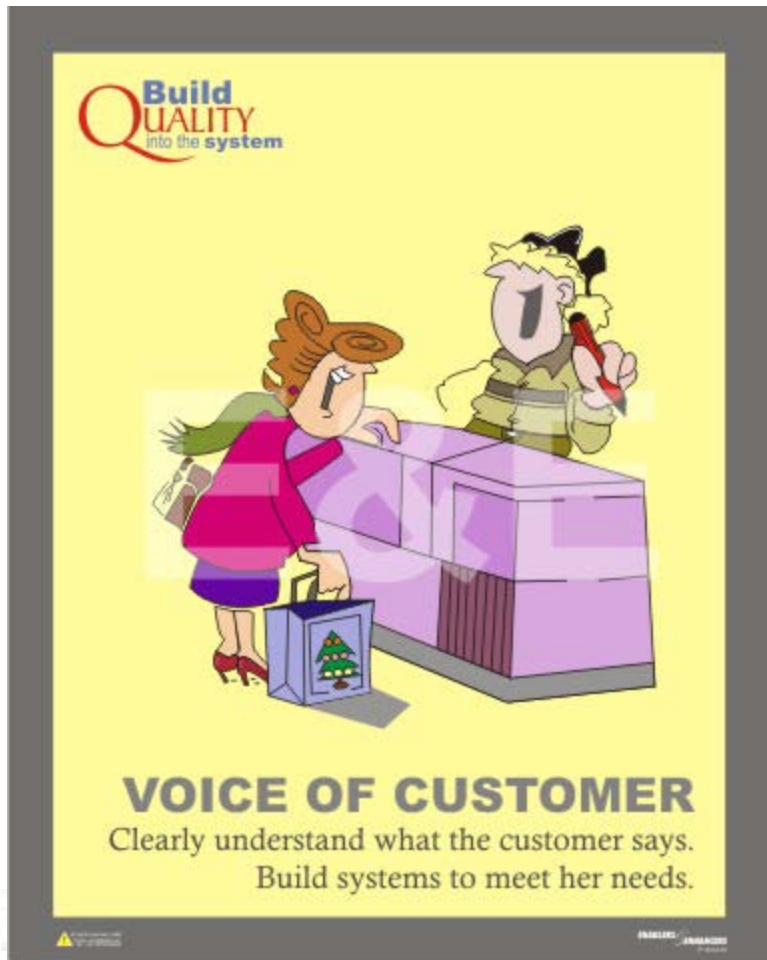


WHAT THE CUSTOMER WANTED!!!

"COMMUNICATION" MEANS: SAYING AND HEARING HAVE THE SAME MESSAGE

Tree Swing picture from 1970s - Businessballs.com (Ack T & W Fleet)

VOC and Planning



Elements of Design Control:

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Verification and Validation

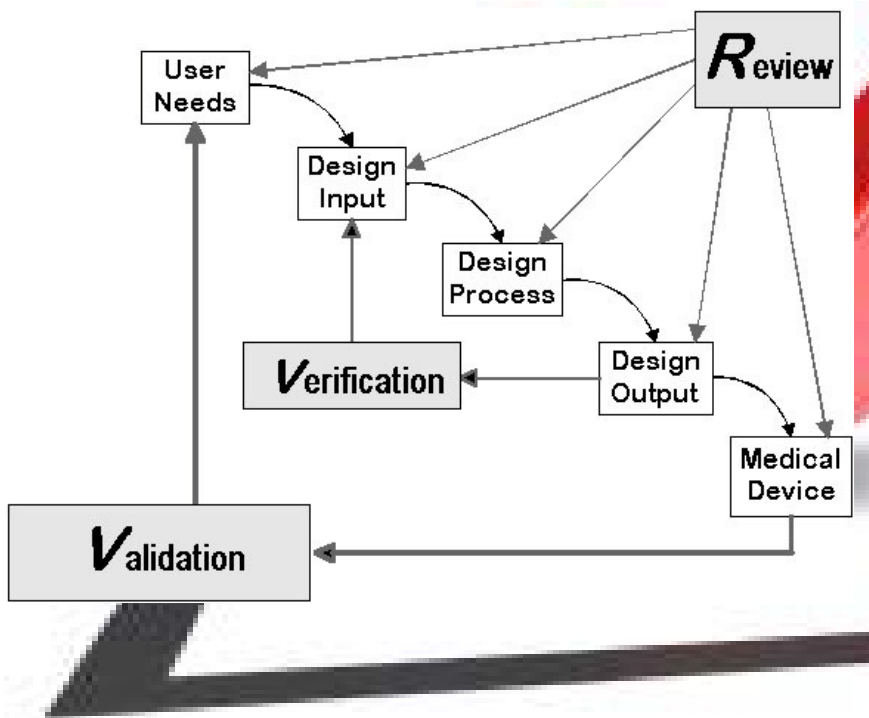
Reasons for V&V Activities

Verification

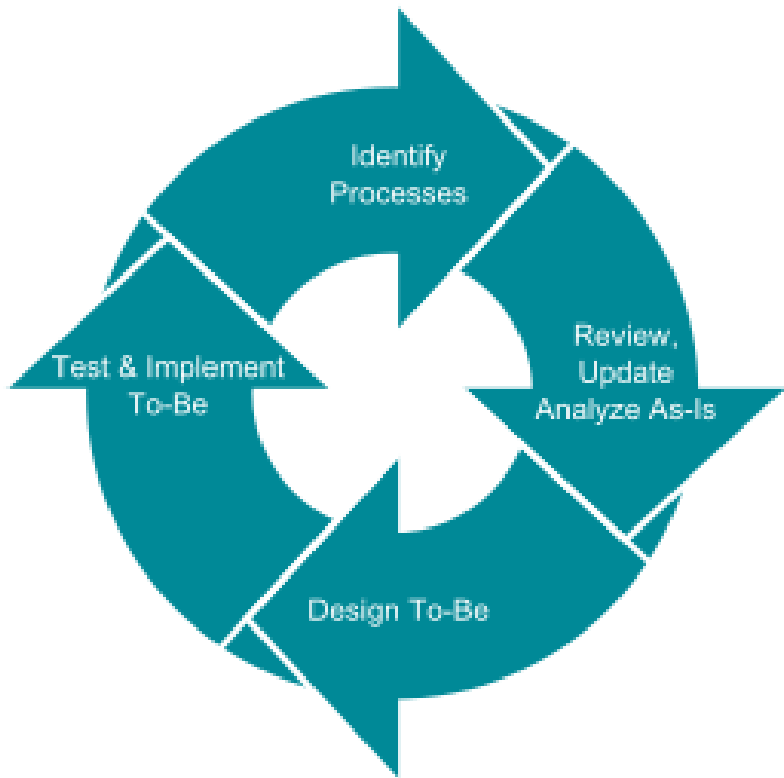
- Assure Design Output meet the needs of the design input
- Assure product is reliable and risk is acceptable

Validation

- Assure device meets the customer needs
- Assure usability of device



Change Control



Business Process Reengineering Cycle

Change Drivers

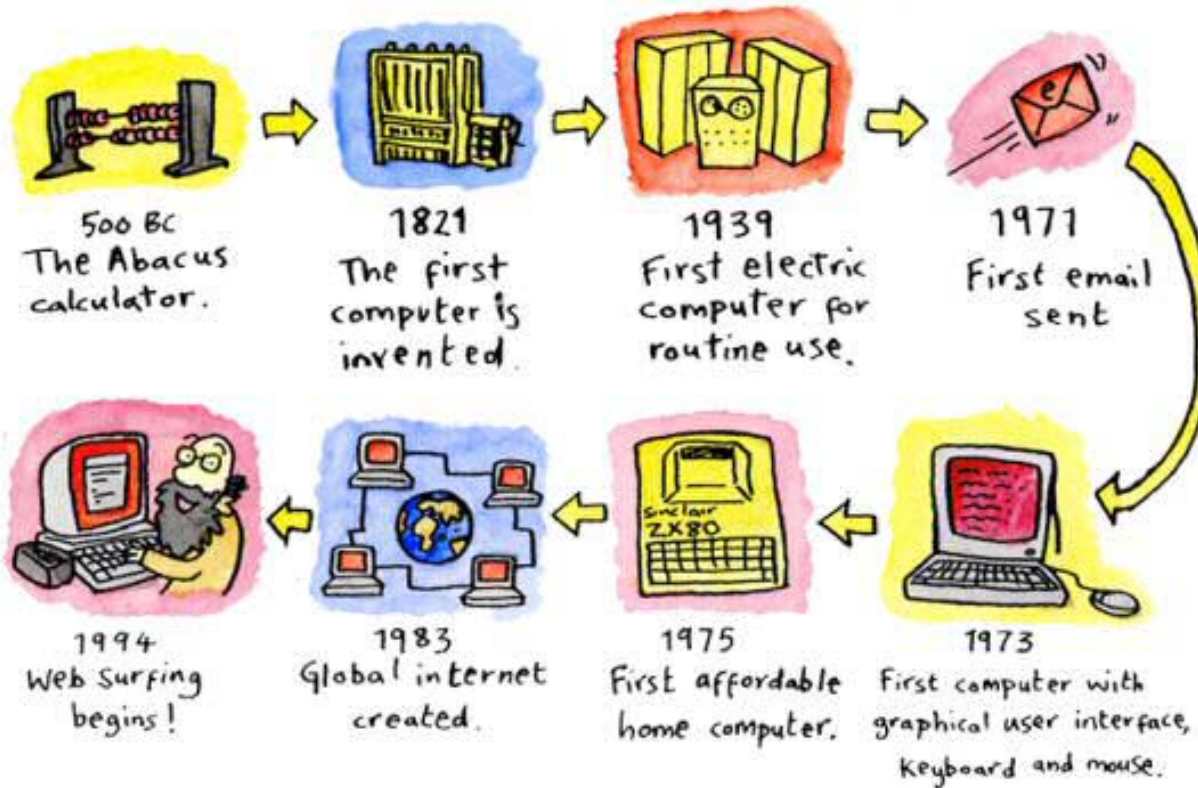
- Customer requests
- Quality Improvement
- Improved Reliability
- Reduce Risk

Implementation

- Design Verification has to be very thorough to assure reliability and safety is not compromised
- Planning is critical

History of Technology

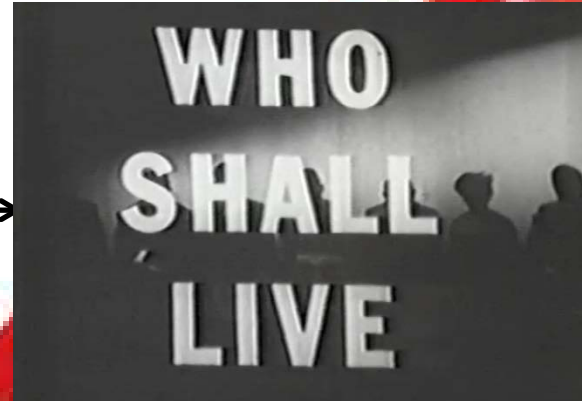
⚡ Techie Timeline ⚡



History of Dialysis Followed



Treatment for Kidney Failure Possible



Not everyone could get treatment



Treatments became safer, efficient and widely available



Technology takes over

Future of Dialysis Technology



Key Drivers

- Cost restrictions from government
- High operational cost for clinics
- Improved Online Diagnostics
- Strong desire for improved patient mobility

Future of Dialysis Technology

Automation

- Simplified Setup
- Reduce time allowing staff to focus more on patients
- Decreased chance of error during setup
- Improved Safety



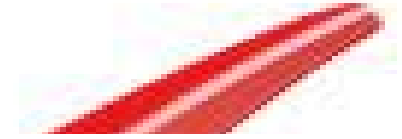
Future of Dialysis Technology

Micro Technology

- Wearable kidneys
- Allows 24/7 therapy
- Patients do not need to change lifestyle
- Maximum Mobility



Conclusion



Process

- FDA has improved their regulations emphasizing VOC and Reliability Verification
 - Improves quality of product, but increases time to market

Technology

- Dialysis technology has been driven by two factors:
 - Available Technology
 - Cost restrictions from government reimbursement

QUESTIONS?



References

- <http://homedialysis.org/home-dialysis-basics/machines-and-supplies/dialysis-museum>

