Usability Testing:

Why can't we get it right?

presented by:

Michael Drues, Ph.D.

President, Vascular Sciences
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and

Adjunct Professor of Regulatory Science, Medicine and Biomedical Engineering

Cornell University Graduate Dept. of Biomedical Engineering

Greenlight Guru (September 22, 2022)

https://www.greenlight.guru/webinar/usability-testing

For questions or more information, call
(508) 887 – 9486 or e-mail mdrues@vascularsci.com

Usability Testing: *Why can't we get it right?*

presented by: ***Michael Drues, Ph.D.***

Usability testing (a.k.a. human factors or ergonomics) has become the rule rather than the exception for most regulated medical devices. In fact, FDA has published at least six guidance documents involving usability or human factors for medical devices and combination products since 2016. Regrettably, for many in this industry usability testing has become nothing more than a tick-box on a form!

Yet in spite of these usability requirements (or perhaps because of them), we continue to experience significant user-related problems with many important medical devices – *why?* And these problems are often not discovered until after the device is FDA cleared or approved and on the market – *why?*

In this webinar, some of the questions to be discussed include:

- What is usability testing and more importantly, why is it important?
- Why is usability testing the rule rather than the exception? Was it always this way?
- Does usability differ for devices used by patients vs. devices used by healthcare professionals?
- How does usability differ pre-market vs. post market?
- How can we do usability testing better while still ticking the regulatory boxes?
- What are the usability challenges in the future (i.e., personalized devices) and how to we meet them?

This webinar will not take the typical approach to usability testing. In his signature style, Dr. Michael Drues will use actual devices as case studies to take a critical look at the way we do usability testing today and ask the seemingly simple question: *does what we do make sense?*

About the Presenter

Michael Drues, Ph.D., is a regulatory strategy consultant specializing in designing novel regulatory strategies to bring new and innovative medical products to market and in developing effective communication strategies between companies and regulatory agencies to minimize time to market and avoid delays.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University. He works with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration, Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short courses for medical device, pharmaceutical and biotechnology companies, the FDA, Health Canada, the US and European Patent Offices, CMS and other regulatory and governmental agencies around the world.

Finally, Dr. Drues is an Adjunct Professor of Regulatory Affairs, Medicine and Biomedical Engineering at several universities and medical schools. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Product Development, Combination Products and Pathophysiology.

Additional Resources

- Global Medical Device Podcast: ***Setting the Record Straight on Usability*** (Nov, 2021) here
- Conference Debate: *The Two Sides of Human Factors* (MPO Summit, Sept 2021) here.
- Mike on Medtech: ***Human Factors/Usability*** (MPO, Feb, 2020) Part 1 & Part 2
- Global Medical Device Podcast: ***The Intersection of Usability and Risk*** (April, 2017) here.
- Global Medical Device Podcast: ***Challenges related to Home Use Devices*** (Sept, 2020) here
- Mike on Medtech: ***Importance of human factors in device devlpmnt*** (MPO, Oct, 2017) here.

For additional information, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com or via LinkedIn at www.linkedin.com/in/michaeldrues.

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Want the handout? podcast?

Connect with me on LinkedIn or give me your business card!

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Usability Testing: *Why can't we get it right?*

Introductions

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Do you want more?

Global Med Dev Podcast (GreenLight.Guru) here
Mike on MedTech (Medical Product Outsourcing) here
Medical Design and Outsourcing here
Guerilla Regulatory Strategy (MED Device Online) here
Healthcare Packaging here
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Usability Testing: *Why can't we get it right?*

First, an important disclaimer...

I can't make you an expert in a few minutes!

I'm not even going to try but…

Remember my philosophy of education:

To teach you how to think not what to think!

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Here's what we'll talk about…

- ✓ What is usability testing and more importantly, why is it important?
- ✓ Why is usability testing the rule rather than the exception? Was it always this way?
- ✓ Does usability differ for devices used by patients vs. devices used by healthcare professionals?
- ✓ How does usability differ pre-market vs. post market?
- ✓ How can we do usability testing better while still ticking the regulatory boxes?
- ✓ What are the usability challenges in the future (i.e., personalized devices) and how to we meet them?
- ✓ Bonus: What's the difference between a usability study *vs.* a clinical trial?
- ✓ Lots more tips and tricks… time permitting!
- ✓ Final thoughts…

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Usability Testing: *Why can't we get it right?*

What is usability testing and more importantly, *why* is it important

Simple answer:

"Evaluating a product by testing it with representative users."

But what does that mean?

How do you evaluate it? *i.e., on-label vs. off-label?* What about anticipated off-label use?

When do you evaluate it? *i.e., formative vs. summative testing*

Who are these *representative users*? i.e., patients? HCP's? both? someone else?

How many users? How many groups? Where should the evaluation be done? etc., etc., etc.

Mike's Recommendation:

Your answers should be based on common sense – not "regulatory requirements!"

And your answers should be defendable!

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Don't just follow the rules… think!

Rules are mostly made to be broken

and are too often for the lazy to hide behind.

General Douglas MacArthur (1880 –1964) was an American general in the US Army during the 1930s and played a prominent role in the Pacific theater during World War II. He was one of only five men ever to rise to the rank of General of the Army in the U.S.

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Usability Testing: *Why can't we get it right?*

What is usability testing and **more importantly, *why* is it important**

Simple answer:

"to demonstrate your device can be used as intended"

Drues, 2022

Example:

Cars vs. Coronary Stents

Important Reminder:

Ticking the regulatory boxes does NOT necessarily mean you have done this!

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Why is usability testing the *rule* rather than the *exception?* Was it always this way

Can you say

Infusion Pumps!

How? Why?

Video: *Infusion Pumps* (FDA Patient Safety News) (2 min)

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Usability Testing: *Why can't we get it right?*

Major Usability Guidance Documents

Guidance	Issue Date	FDA Center
Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to **Drug and Biologic Applications**	10/1/2018	CDER
Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device **Combination Product** Submitted in an ANDA	1/17/2017	CDER/CDRH
Human Factors Studies and Related Clinical Study Considerations in **Combination Product** Design and Development	2/3/2016	CDRH/CDER
Applying Human Factors and Usability Engineering to **Medical Devices**	2/3/2016	CDRH
List of Highest Priority **Devices** for Human Factors Review	2/3/2016	CDRH

FDA Guidance Document Database here

What happened before 2016?

Should FDA regulate usability? [formative vs. summative]

Why do we need "big brother" to tell us we should do this?

Note: CDRH vs. CDER vs. CBER – does it matter? / Make sure you have the right people in the room!

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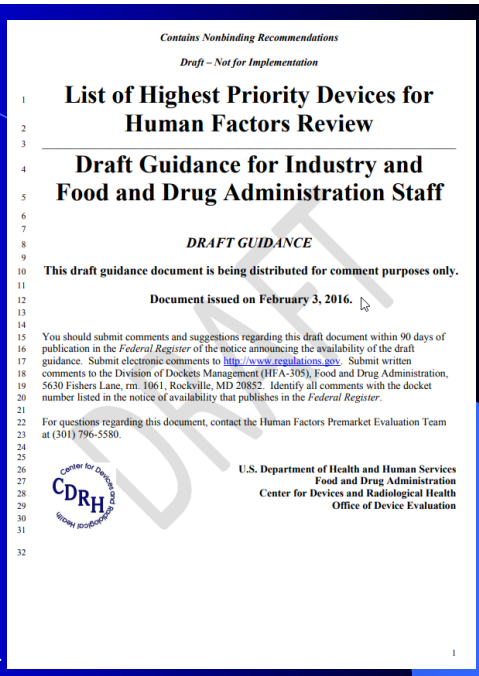
Be very, very careful

using this guidance! →

CDRH Guidance here.



Contains Nonbinding Recommendations

Draft – Not for Implementation

List of Highest Priority Devices for Human Factors Review

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on February 3, 2016.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

DRAFT

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Usability Testing: *Why can't we get it right?*

Regulatory logic substantially equivalent here – pun intended! ☺

Be very, very careful

using this guidance as well! →

CDRH Guidance here.

Contains Nonbinding Recommendations

Draft – Not for Implementation

Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on October 15, 2020.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

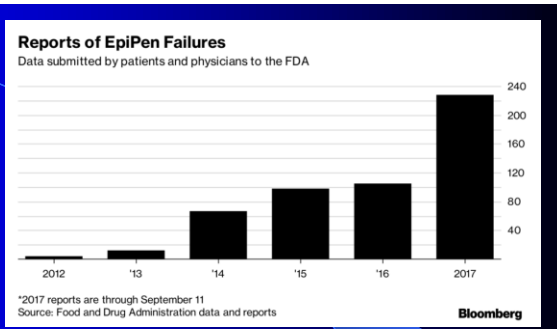
For questions about this document, contact the Office of Product Quality and Evaluation (OPEQ)/Clinical and Scientific Policy Staff at CDRH.Biocomp@fda.hhs.gov or (301)-796-5701.

When final, this guidance will update Sections II and III and add a new Attachment to "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" issued on June 16, 2016.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Case Study: *EpiPen*



EpiPen Failures Cited in Seven Deaths This Year (Bloomberg, Nov. 2, 2017) here.

Video: *EpiPen failures (CBS NEWS November 3, 2017) (3 min)*

Why is this happening?

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Usability Testing: *Why can't we get it right?*

Does usability differ for devices used by patients vs. devices used by healthcare professionals

Short answer:

Absolutely… at least in theory!

i.e., Importance Useability $_{\text{Patients}}$ >> Importance Usability $_{\text{Healthcare Professionals}}$! – ***why?***

But no where in the regulation / guidance is this written… should it be?

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Does what we do make sense?

Compare and contrast two recent devices:

Intraocular Injection

Spit in a Tube (saliva-based IVD)

In which case is usability more important / more critical?

Zero usability testing

[510k → "well-established" technology]

(usability not necessary?!?!?)

Extremely extensive usability testing (510k AIR Hold Letter)

[De novo → "new" technology… but not spit part!]

Throw least-burdensome flag! (podcast)

Root Cause:

Following regulation like a mindless automaton, i.e., without thinking!

Mindless Automaton: person who follows instructions blindly and to the letter never exercising judgement or common sense (here)

Regrettably, ***this is what gives regulatory a bad name!*** ☹

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Usability Testing: *Why can't we get it right?*

How does usability differ pre-market *vs.* post market

Pre-Market:

Formative HF (forms/shapes design during development)

+

Summative HF (issues/problems/benefits of existing/prototype design)

+

What's missing?

Post-Market:

Human Factors Post-Market Surveillance!

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Talk is cheap...

Is this theory or reality?

Human Factors and Postmarket Surveillance here

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Usability Testing: *Why can't we get it right?*

Case Study: *da Vinci surgical robot*

At the end of the day...

Video: *The da Vinci surgical robot: A medical breakthrough with risks for patients* (NBC News, Dec, 2018) (4 min) here.

Video: *Robotic surgery is high-tech but is it safe* (NBC, June 17, 2013) (9 min) here.

Questions for Discussion:

1. What is the *root cause* of this problem? Hint: is lack of training the *real* root cause? How much training is enough?
2. Were these problems *unforeseeable*, i.e., *anticipated risks?* Were these problems new?
3. How does human factors / usability fit into this equation?
4. Who's to blame? FDA: "does not have jurisdiction" / Manufacturer: "cannot require training" Is this a copout?
5. Speaking of blame… what happens when we get it wrong? Video: *Da Vinci Robot Surgery Lawyers* (30 sec)
6. Does it make sense to separate the efficacy of the device from the skill level of the user?
7. How is this similar to Enteryx?
8. What are the lessons to be learned? What else is important?

How can we do usability testing better while still ticking the regulatory boxes

Example:

How do we typically do usability testing today?

Mike's wackadoodle two-step usability protocol:

Step 1: Give device to user

Step II: You can stop talking now!

Rhetorical Question:

Is this really so wackadoodle after all?!? Is it possible? Is it *possimpible*?

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Usability Testing: *Why can't we get it right?*

What's *Possimpible?*

The Possimpible (How I Met Your Mother, February 2, 2009)

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What are the usability challenges in the future (i.e., personalized devices) and how to we meet them

Short answer:

That's a topic for a much more advanced discussion!

It will require a totally different approach, i.e., different thinking…

but the regulatory logic is *substantially equivalent*.

Pun intended! ☺

Case Study: *3DP*

Case Study: *3DP Stent*

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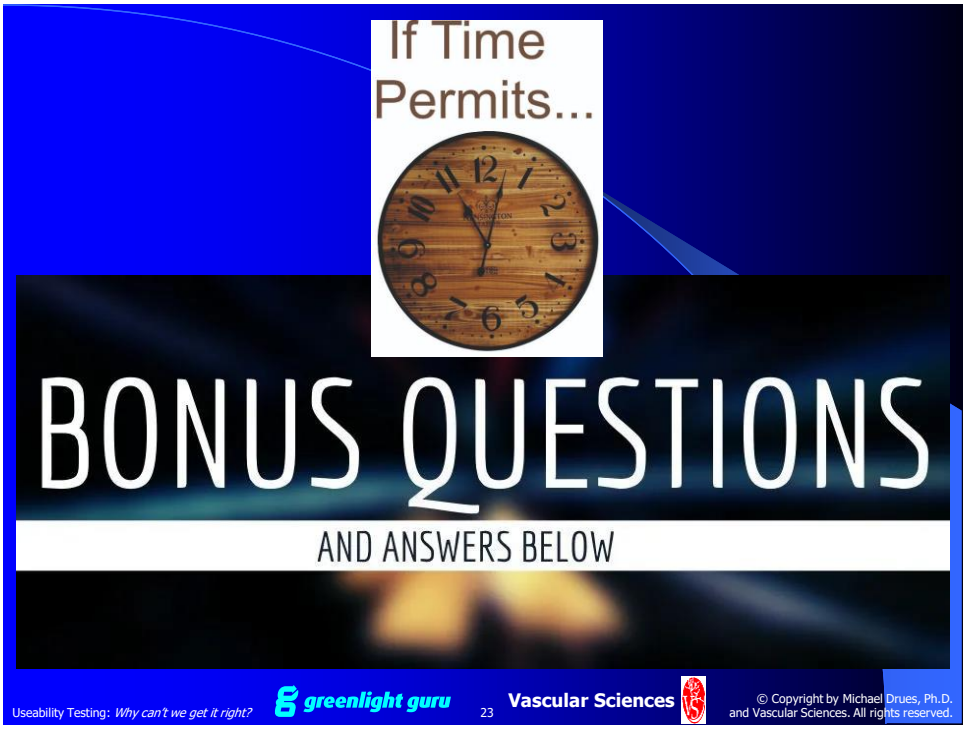

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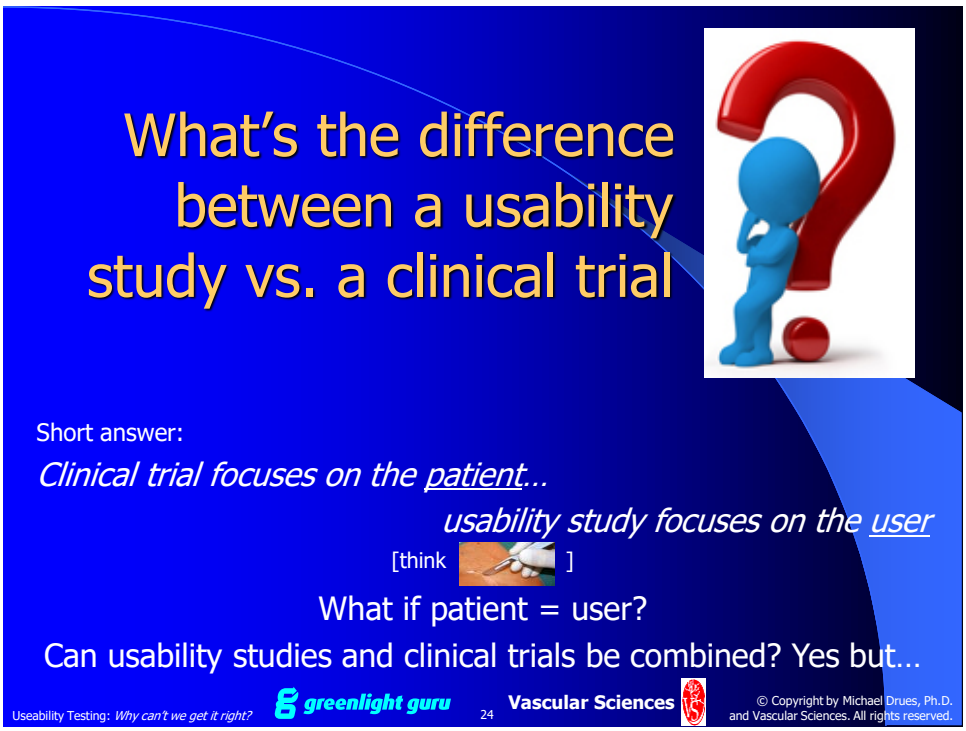

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Usability Testing: *Why can't we get it right?*

What's the TAKE AWAY

Do useability testing if and when necessary…

not because its required… but because it's the responsible thing to do!

Reminder: *the surgery went perfectly but the patient died anyway!*

Do useability testing realistically…

*this is **not** required… but it is the responsible thing to do!*

Reminder: *Regulatory vs. Product Liability*

Do usability testing pre-market…

but don't forget the importance of usability post-market!

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Here's what we talked about…

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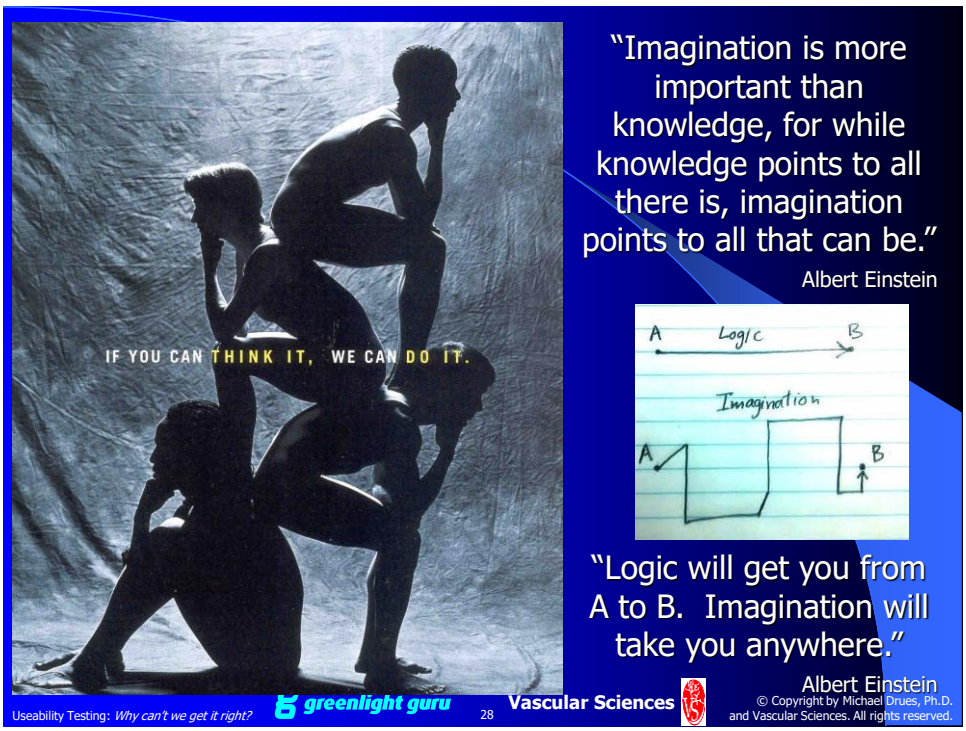

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Usability Testing: *Why can't we get it right?*

Taking inspiration from one of best…

"Here's to the crazy ones. The misfits. The rebels. The troublemakers. The round pegs in the square holes. The ones who see things differently. They're not fond of rules. And they have no respect for the status quo. You can quote them, disagree with them, glorify or vilify them. About the only thing you can't do is ignore them. Because they change things. They push the human race forward. And while some may see them as the crazy ones, we see genius. Because the people who are crazy enough to think they can change the world, are the ones who do."

Steve Jobs (1955 – 2011), entrepreneur, marketer and inventor, the co-founder of Apple Inc. and widely recognized as a pioneer of the personal computer revolution.

Steve Jobs Heres To The Crazy Ones (1 min)

More importantly…

"Imagine where we could be if discontent for the status quo was the norm rather than the exception."

Can you guess who said this?

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Questions?
Comments?
Suggestions?
Criticisms?
Complaints?

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