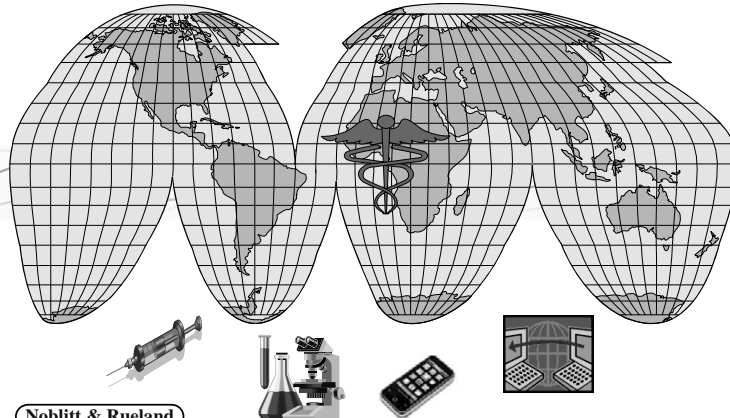


# UCI Medical Device Regulatory Awareness - Implications for Start-ups -



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## Noblitt & Rueland

- Consulting & Training Company
- >26 Years
- Specializing in FDA & ISO related issues
- Primarily focused on medical device regulatory & quality
- Trained over >5000 medical device manufacturing employees on numerous FDA & ISO topics
- Consulting on Medical Device submissions, 510(k), CE Mark, PMA submissions, compliant quality systems, QSR/GMP, ISO 13485, auditing, software, Risk Analysis, Design Control, IEC 60601-1, Electronic Recordkeeping, clinical studies, and FDA enforcement problems, etc.

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## Brent Noblitt Biography

**Brent Noblitt** is co-founder and Senior Partner of the consulting firm Noblitt & Rueland. Mr. Noblitt specializes in international and U.S. medical device strategic planning, development, and marketing. His consultation has been used to market medical devices throughout the world. Mr. Noblitt's associations range from start-up ventures to Fortune 100 corporations. His marketing background and technical training allows him to comprehend and advise on the marketing planning process and opportunities of various technologies. Prior to founding Noblitt & Rueland, Mr. Noblitt held management & executive positions in the medical device industry. Mr. Noblitt's product experience includes various critical care devices, cardiac output computers & pulmonary catheters, extravascular lung water computers, ultrasound devices, phono-angiography, computerized patient databases, patient monitoring systems, disposable & reusable pressure monitoring devices & accessories, ejection fraction computers, continuous mixed venous oxygen saturation systems & catheters, surgical laser systems, implantable defibrillators, pacemakers, continuous blood pressure control systems, as well as, home healthcare delivery systems. His academic training includes a B.S. and M.S. in Electrical Engineering-Biomedical from Purdue University complemented by an M.B.A. degree earned from Pepperdine University and he is a member of ASQC-Biomedical & Healthcare Divisions, Association for the Advancement of Medical Instrumentation (AAMI), and the Orange County Regulatory Affairs Association (OCRA).

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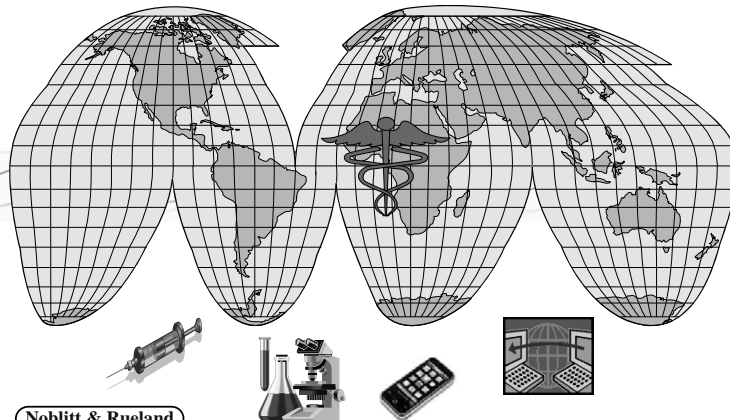
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# Medical Device Regulatory Awareness Training

## ● SESSION OBJECTIVES

- Gain insight into regulations for medical devices especially as related to Start-up companies.

## Regulatory Overview (US Focus)



## FDA Purpose

U.S. FDA = United States Food and Drug Administration

- Government watch dog over Foods, Drugs, Devices, Cosmetics, etc.
- Protect Public Health
  - Establish controls
  - Review & inspect safety & efficacy of medical devices
  - Regulate design & manufacturing
    - Inside US &
    - Outside US for use in US
  - Expects documentation: "Not written down it didn't happen."
- FDA takes their responsibility very seriously...they carry a big stick! Not just a traffic cop.
- Los Angeles District Office ~2 miles away (new people)

How does FDA protect  
the public health?



**THROUGH  
ENFORCEMENT**

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## FDA Enforcement Tools

- NAI (No), VAI (Voluntary), OAI (Official Action Indicated)
- 483 Observations (inspections)
- Warning Letters
- Recalls
- Seizure
- Consent Decree
- Injunction
- Prosecution
- Civil Penalties
- Debarment from industry
- Import Detention
- Criminal Proceedings, etc.
- Withdrawal of Product Approval
- Disqualification (clinical investigators)

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## Other ways FDA protects that will have major impact on a start-up

- Not Approving or Clearing Medical Device Submissions
- Product Recalls (example: recalling a product sold without a required approval or clearance)
- FDA facility inspection findings that lead to a Warning Letter or worse (public information)

## Basic Manufacturer Requirements

- Registration & Listing with FDA
- Submissions...leading to regulatory approval or clearance to legally market a medical device in U.S.
  - Exempt, non-exempt, 510(k), PMA, De Novo
- Quality system...a controlled & documented process for manufacturing a medical device in compliance with a regulatory body's requirements/regulations. (This assumes a start-up is going to actually manufacture the device.)
  - 21 CFR Part 820 Compliant (similarities to ISO 13485, ISO 9001)
  - FDA will inspect (goal is every 2 years)
- California companies must also be licensed by the state.
  - \$2080/1<sup>st</sup> year, \$3380/2 yrs, will inspect very quickly

## Start-up Regulatory Considerations

- Regulatory Strategy
  - Classification of Product/Device
  - Required regulatory avenue
- Regulatory Costs
- Organization Infrastructure
- Exit Strategy thoughts
- Recommendations

## Classification & Regulatory Strategy

- Need to determine the Device classification early (critical)
- Is it a Device by FDA Definition? Wellness product?, etc.
- Class I or Class II exempt (no submission required)
- Class I or Class II non-exempt
  - 510(k) submission required (\$ to \$\$), FDA fee: \$4,690 / \$2345
  - Must show substantial equivalence to a predicate device
  - Clear predicate(s) identifiable? If not, De Novo route feasible?
- Class III
  - Most Class III devices require PMA (\$\$\$ to \$\$\$\$\$)
  - FDA fee: \$235K / \$59K / \$0 (1<sup>st</sup> PMA fee waived if <\$30 mill)
  - Probability of approval mainly based on achieving clinical endpoints during clinical studies (\$\$\$)
- Examples from FDA database...

# Device Example A



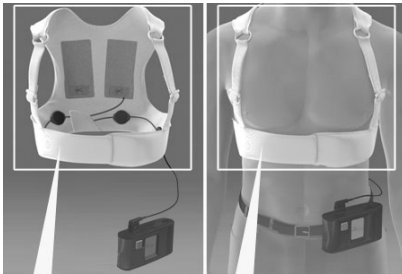
<b>Device</b>	Over-the-counter Powered Light Based Laser For Acne
<b>Regulation Description</b>	Laser surgical instrument for use in general and plastic surgery and in dermatology.
<b>Definition</b>	The device is intended for over-the-counter (otc) use to treat patients with mild to moderate acne vulgaris. The device is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne vulgaris.
<b>Physical State</b>	Light Source: LED
<b>Technical Method</b>	The outputs are pre-tuned to a particular wavelength with a narrow spectral bandwidth.
<b>Target Area</b>	Mainly on the face, but can be on the back or on the other parts of the body. Treatment area is 5x6 cm (at a time.)
<b>Regulation Medical Specialty</b>	General & Plastic Surgery
<b>Review Panel</b>	General & Plastic Surgery
<b>Product Code</b>	OLP
<b>Premarket Review</b>	<a href="#">Office of Device Evaluation (ODE)</a> Division of Surgical Devices (DSD) General Surgery Devices Branch One - Light Based/Laser (GSDB1)
<b>Submission Type</b>	510(k)
<b>Regulation Number</b>	<u>878.4810</u>
<b>Device Class</b>	2
<b>Total Product Life Cycle (TPLC)</b>	<u>TPLC Product Code Report</u>
<b>GMP Exempt?</b>	No
<b>Recognized Consensus Standards</b>	<ul style="list-style-type: none"> <li>● IEC 62471 First edition 2006-07 <a href="#">Photobiological safety of lamps and lamp systems</a></li> <li>● ANSI/IESNA RP-27.1-2005 <a href="#">Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - General Requirements</a></li> <li>● ANSI/IESNA RP-27.3-2007 <a href="#">Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification and Labeling</a></li> <li>● ANSI/IESNA RP-27.2-2000 (Reaffirmed 2011) <a href="#">Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - Measurement Techniques</a></li> </ul>
<b>Implanted Device?</b>	No
<b>Life-Sustain/Support Device?</b>	No
<b>Third Party Review</b>	Not Third Party Eligible

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# Device Example B



<b>Device</b>	Wearable Automated External Defibrillator
<b>Definition</b>	The device is an automatic external defibrillator which monitors and treats a patient for ventricular defibrillation. Device is intended to be worn in home or in hospital settings as prescribed and overseen by a physician.
<b>Review Panel</b>	Cardiovascular
<b>Product Code</b>	MVK
<b>Premarket Review</b>	<u>Office of Device Evaluation (ODE)</u> Division of Cardiovascular Devices (DCD) Cardiac Diagnostics Devices Branch (CDDDB)
<b>Submission Type</b>	PMA
<b>Device Class</b>	3
<b>Total Product Life Cycle (TPLC)</b>	<u>TPLC Product Code Report</u>
<b>GMP Exempt?</b>	No
<b>Recognized Consensus Standards</b>	<ul style="list-style-type: none"> <li>● AAMI/ANSI/ISO 27185:2012 <u>Cardiac Rhythm Management Devices -- Symbols to be Used With Cardiac Rhythm Management Device Labels, and Information to be Supplied -- General Requirements</u></li> <li>● ISO 27185 First edition 2012-02-15 <u>Cardiac Rhythm Management Devices - Symbols to be Used With Cardiac Rhythm Management Device Labels, and Information to be Supplied - General Requirements</u></li> </ul>
<b>Implanted Device?</b>	No
<b>Life-Sustain/Support Device?</b>	Yes
<b>Third Party Review</b>	Not Third Party Eligible

Difference & Impact: Example B vs Example A  
Probably >\$1+ Million, several years to market  
and a lot more regulatory & liability risk

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# App Example



<b>Device Classification Name</b>	<u>Electrocardiograph</u>
<b>510(k) Number</b>	K122356
<b>FOIA Releasable 510(k)</b>	<u>K122356</u>
<b>Device Name</b>	ALIVECOR HEART MONITOR FOR IPHONE
<b>Applicant</b>	ALIVECOR, INC. 140 Geary Street Suite 500 San Francisco, CA 94108
<b>Applicant Contact Correspondent</b>	Michael Righter ALIVECOR, INC. 140 Geary Street Suite 500 San Francisco, CA 94108
<b>Correspondent Contact</b>	Michael Righter
<b>Regulation Number</b>	<u>870.2340</u>
<b>Classification Product Code</b>	<u>DPS</u>
<b>Date Received</b>	08/03/2012
<b>Decision Date</b>	11/19/2012
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	Cardiovascular
<b>510k Review Panel</b>	Cardiovascular
<b>Statement</b>	<u>Statement</u>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No

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# App Example

<b>Device</b>	Electrocardiograph
<b>Regulation Description</b>	Electrocardiograph.
<b>Regulation Medical Specialty</b>	Cardiovascular
<b>Review Panel</b>	Cardiovascular
<b>Product Code</b>	DPS
<b>Premarket Review</b>	<u>Office of Device Evaluation (ODE)</u> Division of Cardiovascular Devices (DCD) Cardiac Diagnostics Devices Branch (CDDB)
<b>Submission Type</b>	510(k)
<b>Regulation Number</b>	<u>870.2340</u>
<b>Device Class</b>	2
<b>Total Product Life Cycle (TPLC)</b>	<u>TPLC Product Code Report</u>
<b>GMP Exempt?</b>	No
<b>Recognized Consensus Standards</b>	<ul style="list-style-type: none"><li>• IEC 60601-2-25 Edition 2.0 2011-10 <u>Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs</u></li></ul>

So all health apps are medical devices?  
No...some are considered wellness products  
which are not considered medical devices.  
Be very, very careful! Guidance is available.

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## Regulatory Costs

- If 510(k) Submission required
  - Generally speaking, \$3K - \$50K++ to achieve FDA 510(k) clearance, when testing costs are included & depending on the device
  - ~90-180+ days from submission to FDA clearance (if well written)
- If PMA Submission required, in general >\$100K - \$1M++ to achieve FDA approval
  - Substantial clinical data/trials needed
  - ~250 days to 3+years from submission to approval
- FDA Establishment Registration Fee \$3,382/yr (FY 17)
- Quality System (GMP) implementation required? Not trivial to implement or maintain. FDA will inspect. Personnel needed?

## Organization Infrastructure

- Brick & Mortar vs Virtual Company
- Virtual Company Infrastructure is acceptable by FDA
  - Utilization of consultant(s) for regulatory expertise
    - Submissions & installation of Quality System if necessary
  - Design & manufacturing can be done by vendors (i.e. contract manufacturers)
- Internal hire vs External consultant
  - At a minimum, periodic ongoing regulatory/quality support will be needed

## Company / Investor Exit Strategy Thoughts

- If exit strategy is to obtain 510(k) clearance and divest the company or sell the submission, a quality system may not be needed (i.e. no manufacturing planned)
- A Quality System and manufacturing are not required to obtain 510(k) clearance...however elements of a QS may be needed for a submission (i.e. Design Control, Risk Management, Software Quality Assurance, etc.). If manufacturing is planned, a FDA compliant Quality System will be required.
- Quality System is needed for PMA approval or to manufacture a Medical Device in most cases.
  - FDA will inspect prior to granting PMA approval

## Recommended Start-up 1<sup>st</sup> Step: Regulatory Assessment

- Perform or have a regulatory assessment done by someone knowledgeable and experienced in medical device regulations (decipher gray areas)
- Benefits
  - Understand
    - regulatory pathway (classification, etc.)
    - clinical studies & what testing is required (\$)
    - potential regulatory costs (\$ to \$\$\$\$\$)
    - likely regulatory timeline/delays (mos to years)
    - regulatory risks
  - Marketing/Financial Strategy mesh with Regulatory Requirements?  
ex. Prescription vs OTC (over-the-counter), 510(k) vs PMA
  - Provides information for an intelligent discussion with potential investors & financial planning

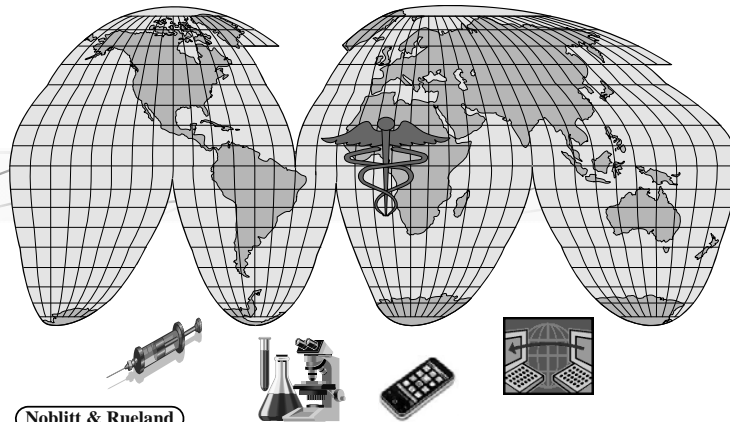
## Start-up: Product Development Recommendation

- Development vs Feasibility?
- Recommendation: Create & Document a Design Control process for development; especially,
  - Design Control
    - FDA will expect/require compliance with Design Control requirements 21 CFR Part 820.30
    - Submission & eventual Quality System
  - Risk Management (part of Design Control)
    - Risk and Hazard Analysis (submission & quality system)
  - Software
    - FDA expects/requires software to be developed under a defined and documented process as part of Design Control
- Creating retrospective documentation is no fun!
- Benefits: creation of high quality, safer devices quicker and achieve FDA clearance faster.

## Good Luck!

- Welcome to the medical device world!
- More info & questions?
  - MDM, booth 1508
  - Call/email with questions
  - Training Medical Device courses offered
    - Anaheim, Disney Resort, July 10-14, 10 courses
    - See [www.fdaconsulting.com](http://www.fdaconsulting.com) for more info

# Thank You!



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## Hot/New Regulatory Topics

- Presidential Election...New Commissioner? New Direction? Less regulation?
- New ISO 13485:2016 released
- CE Marking (Europe) major changes coming, MDR
- Single Audit Pilot Program, MDSAP, (U.S., Australia, Brazil, Canada, and Japan)
- Device Tax (2.3%), totally repealed soon?
- Cybersecurity, Post Market Surveillance, etc.
- Risk / Benefit
- Recalls (increase in recent years)
- UDI (Unique Device Identification)
- Usability / Human Factors
- 21 Century Cures Act, Device Clauses

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**Summer 2017 Training Schedule Announced!**  
**Be Prepared for enforcement and new regulations!**

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Registration & more info at:  
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or call 1-888-892-4664

## Important Medical Industry Training Programs

- 10 courses in one week, dual tracks, attend one or more, mix & match -

Important Updates!

Revised Standard!

Prepare Now!

- **FDA QSR/GMP/ 21 CFR Part 820 & FDA Inspections** July 10
- **Auditing Quality Systems for FDA & ISO Compliance** July 11
- **ISO 13485:2016 ...Changes & Compliance Challenges** July 12
- **Complaints, MDRs & CAPA for Devices** July 13
- **Process Validation for Medical Device Compliance** July 14
- **Design Control, FDA & ISO** July 10
- **Risk Management, ISO 14971 & FDA Requirements** July 11
- **Software Verification & Validation Strategies\*** July 12
- **CE Marking: Medical Devices & IVDs (major changes coming!)** July 13
- **510(k) Submissions: How to's, Strategies & Tactics** July 14

\*Includes device/product, quality system, manufacturing, process, test, statistical, clinical, custom, off-the shelf, and 3<sup>rd</sup> party software, as required by FDA's GMP/QS regulations, Part 11, IEC 62304, Agile, APPs and new ISO Stds.

### These courses provide:

- How to comply with FDA QS Reg & **New** ISO 13485:2016 requirements.
- Preparation for FDA Inspections, ISO/EN audits and 510(k) & CE Mark.
- Latest guidance (risk mgmt, software, design control, Part 11, 510(k)s, **New** CE marking, quality systems, auditing, new ISO 13485, etc.).
- Current FDA Policies, enforcement activities & methods of prevention.
- How to comply with Complaint Handling, MDR & Process Validation.
- Strategic planning info for FDA, ISO 13485, Intl Stds, Software & 510(k)s.
- Reduced liability risk of Product Safety issues & FDA Enforcement.
- Efficient implementation of Design Control, Risk Management, MDR, Complaint, Software Processes, Part 11 & Quality Systems (FDA, ISO & Canada).
- ...and much more! **See website for complete course information.**



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July 10 - 14, 2017  
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Thank you for your interest in our training.

A complete brochure & web information will be available in the next couple of weeks which will include course descriptions, location/hotel information, registration information & instructions, and instructor biographies. Please check back soon or send us an e-mail to notify you and send a link when it is available.

Please call or e-mail if you have any questions in the meantime.

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Thank you!

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