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The 2003 version of ISO 13485 is organized differently than the 1996 ... identified and described in lower-level procedures or SOPs. The quality manual should be a high-level document, because a ...

ISO 13485:2003: Maintaining Control of Outsourced Processes

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The new ISO 9001:2015
... have combined ISO
9001 and ISO 13485 on
a single certification
certificate. The
divergent specifications
will probably require
separate certification
audits and a separation
...

**ISO 9001 and ISO
13485: New Risk
Management**

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Requirements Present Challenges

Natera, Inc. (NASDAQ:
NTRA), a pioneer and
global leader in cell-free
DNA testing, today
announced it will
present new clinical data
on ...

New Signatera™ Data in Multiple Myeloma, Colorectal Cancer and Ovarian Cancer

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Highlights Clinical Utility of MRD in Real- World Settings

As the pace of innovation further accelerates in 2021, and the need to get new devices to market intensifies, maintaining adherence to regulatory controls is not enough.

Balancing Compliance and Quality in Medical

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Device Manufacturing
Natera, Inc. (NASDAQ:
NTRA), a pioneer and
global leader in cell-free
DNA testing, today
announced initial results
from the ...

**Natera to Present
Clinical Data from
Largest Prospective
MRD-Guided Trial in
Colorectal Cancer at
the 2021 ASCO**

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Annual Meeting

There will be a blood red supermoon across New Zealand and

Australian skies this evening so here's how to capture the perfect photo from your smartphone or camera.

How to photograph tonight's super moon lunar eclipse

The medical device tech

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firm is poised to assist manufacturers in navigating the new European Medical Device Regulation, which goes into effect this week.

Trelleborg helps wearables firms navigate new EU regulation

A COVID-19 test developed by

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PathShodh Healthcare, a start-up incubated at the Society for Innovation and Development (SID), Indian Institute of Science (IISc), has received the license to manufacture ...

IISc start-up gets regulatory approvals for new COVID-19 test
To ensure it meets the high standards expected

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13185 Documents
in the bioprocessing
industry, the unit is
subject to thorough
quality-control
procedures, in
compliance with current
good manufacturing
practice and ISO ...

New Products

The goal of the Swiss
m4m Center in Bettlach
in the canton of
Solothurn is to promote

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these and other ideas 3D printing has made possible. Only opened in September 2020, it has now been successfully ...

Go-ahead for Swiss m4m Center

Earlier had been awarded ISO 9001: 2016: ISO 17100: 2015 and ISO 27001: 2013
"White Globe is proud

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to build a reputation for
quality by gaining
accreditation with the
globally recognized
quality...

**White Globe Achieves
Quintuple ISO
Certifications:
Amongst Select Few
Language Service
Provider's in the
World**

Xiaomi's Poco brand

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sits alongside the Redmi
line as the
manufacturer's
affordable alternative to
its own, Xiaomi-brand
phones, with the Poco
F3 5G being a low-cost
flagship-powered
contender for best ...

**Xiaomi Poco F3 5G
review: a smartphone
with real power at a
super low price**

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Earlier had been
awarded ISO 9001:
2016: ISO 17100: 2015
and ISO 27001: 2013

White Globe has been
awarded the ISO
13485:2016 and ... ISO
certificate was a way to
document, formalise and
improve ...

**White Globe achieves
quintuple ISO
certifications**

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10485 Documents
More than 100
companies that supply
leading-edge products
and services to medical
technology and
biotechnology OEMs
are scheduled to exhibit
at the virtual MD&M |
BIOMEDigital event
next month, and ...

**Virtual Medical
Design and
Manufacturing**

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Exhibition Preview

Capabilities include injection molding; pad printing and laser marking; RF, ultrasonic, and laser welding; solvent and UV bonding; electrical and functional testing; and manual and automated assembly.

Jabil Opens Medical Manufacturing

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Facility in Dominican Republic

Mobility CG, a leading enterprise managed mobility solution provider, today announced a partnership with ImpediMed, a global medical technology company using bioimpedance spectroscopy (BIS) to ...

ImpediMed Selects

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13485
**Mobility CG to
Support Roll-Out of
Proprietary SOZO®
Devices**

Qosina is ISO 13485,
ISO 9001, ISO 22301
and ISO 14001 certified,
and operates in a 95,000
square-foot facility with
an ISO Class 8 Clean
Room. To learn about
Qosina's full
component offering ...

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Qosina Announces Expanded Portfolio for Bioprocess Single-use Systems

Awarded ISO 13485:
2016 and ISO 18587 ...

“The decision to apply for the ISO certificate was a way to document, formalise and improve the way we actually work. White Globe teams invested ...

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White Globe Achieves Quintuple ISO Certifications: Amongst Select Few Language Service Provider's in the World

Through the partnership, Mobility CG provides four different SOZO package configurations that are assembled in accordance with stringent Quality

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Management System
(QMS) and ISO 13485
healthcare ...

**ImpediMed Selects
Mobility CG to
Support Roll-Out of
Proprietary SOZO®
Devices**

Mumbai, Pune,
Maharashtra, India –
Business Wire India •
Awarded ISO 13485:
2016 and ISO 18587 ...

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“The decision to apply
for the ISO certificate
was a way to document,
formalise and improve
the way ...

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