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Joe Gecsey - The
revised ISO 14644
1 changes
classification and
monitoring methods
- Are you prepare
Design History File
DHF, Device Master
Record DMR,

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Device History
Record DHR and
Technical File TF
~~Intro to ISO
14644-1 Room
Classifications NEW
(2019)~~
Classification and
Routine
Environmental
Monitoring for GMP
Cleanrooms

ISO 14644 ~~Intro to
ISO 14644-2 (Part~~

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~~2} - Cleanroom
Particle Sampling
Methods (2019)
Annex 1 2020 Draft
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Are you prepared
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Equivalents ~~Intro to~~
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Basic Introduction

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~~2020 Draft and
Cleanroom
Monitoring Suiting
up to enter our
Class 100
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Cleanrooms: A~~

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Standards ISO
14644 Family
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Explained
LaboGene's new
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Systems Regulation
Requirements -
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ISO 14644-1:2015
does not provide for
classification of
particle populations
that are outside the
specified lower
threshold particle-
size range, 0,1 μm

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to 5 μm .

Concentrations of ultrafine particles (particles smaller than 0,1 μm) will be addressed in a separate standard to specify air cleanliness by nano-scale particles.

~~ISO — ISO~~

~~14644 1:2015 —~~

~~Cleanrooms and~~

Page 10/78

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~~associated ...~~

Concentrations of ultrafine particles (particles smaller than 0,1 μm) are addressed in ISO 14644-12, which specifies air cleanliness by nano-scale particles, while an M descriptor (see Annex C) may be used to quantify

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populations of
macroparticles
(particles larger
than 5 μ m).

~~DIN EN ISO
14644-1:2016
Cleanrooms and
associated ...~~

din en iso 8536-4 :
2013 : infusion
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medical use - part
4: infusion sets for

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single use, gravity
feed (iso
8536-4:2010 + amd
1:2013) din en iso
14644-3 : 2006 :
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controlled
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3: test methods

~~DIN EN ISO
14644-1 : 2016 |
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~~AND ASSOCIATED~~

...

DIN EN ISO
14644-1
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1: Classification of
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14644-1:2015)
standard by DIN-

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environments - part
1: classification of
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~~DIN EN ISO
14644-1 E : 2016 |
CLEANROOMS
AND ASSOCIATED~~

...

This part of ISO

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14644 does not provide for classification of particle populations that are outside the specified lower threshold particle-size range, 0,1 μm to 5 μm .

Concentrations of ultrafine particles (particles smaller than 0,1 μm) will be addressed in a

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separate standard
to specify air
cleanliness by nano-
scale particles.

~~Cleanrooms and
associated
controlled
environments~~

No assumptions are
made regarding the
distribution of the
actual particle
counts over the

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area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling

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to be used in rooms where the particle counts vary in a more complex manner.

~~ISO
14644-1:2015(en),
Cleanrooms and
associated
controlled ...
Comparison of
cleanroom classes
according to DIN~~

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EN ISO 14644-1
and US FED 209D
For the production
of sterile drugs
(pharmaceuticals),
four clean room
classes according to
the EU-GMP
guideline Annex 1
normally apply with
regard to the areas.
The following table
contains the
classification

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according to the
particles contained
in the air.

~~Reinraumklassen
ISO 14644-1 GMP-
Klassen
(Pharmazie) | IAB~~

...

After ANSI and
IEST petitioned to
ISO for new
standards, the first
document of ISO

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14644 was published in 1999, ISO 14644-1. In 2000, ISO 14644-2 was published, which began the process of FED-STD-209E being canceled. On November 29, 2001, the document was canceled and superseded by ISO 14644-1 and ISO

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14644-2. ISO
14644 is now
composed of

~~ISO 14644~~

~~Wikipedia~~

What is

ISO14644-1? •

ISO 14644-1

specifies classes of
air cleanliness in
terms of the
number of particles
expressed as a

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concentration in air volume. • It also specifies the standard method of testing to determine cleanliness class, including selection of sampling locations.

ISO14644-1 is one of the most used standards in Pharma and

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~~Understanding ISO
14644-1/2:2015
and Becoming
Compliant~~

ISO 14644-15:2017
provides
requirements and
guidelines for
assessing the
chemical airborne
cleanliness of
equipment and
materials which are
foreseen to be used

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in cleanrooms and associated controlled environments which are linked to the ISO standard for cleanliness classes by chemical concentration (see ISO 14644 8).

~~ISO ISO
14644 15:2017
Cleanrooms and~~

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~~associated ...~~

DIN EN ISO

14644-14 -

Cleanrooms and

associated

controlled

environments - Part

14: Assessment of
suitability for use of

equipment by

airborne particle

concentration (ISO

14644-14:2016)

Published by DIN

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on January 1, 2017

~~DIN EN ISO~~

~~14644-1-~~

~~Cleanrooms and~~

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controlled

environments - Part

1: Classification of

air cleanliness by

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particle
concentration (ISO
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ISO 14644-1:2015
Edition 2016-06

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The developed standard DIN EN ISO 14644 covers the planning and the operation as well as the monitoring of the cleanrooms.

The ISO 14644 directive family is divided into various parts for this purpose. Whereby parts 1 and 2 cover

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the entire
cleanroom. The
following table
gives you an insight
into the first 5 parts
of DIN EN ISO
14644.

~~ISO 14644 and VDI
2083: connections
and differences~~
ISO 14644-1:2015
does not provide for
classification of

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particle populations that are outside the specified lower threshold particle-size range, 0,1 μm to 5 μm .

Concentrations of ultrafine particles (particles smaller than 0,1 μm) will be addressed in a separate standard to specify air cleanliness by nano-

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scale particles.

~~NUEVA VERSIÓN DE LA NORMA ISO 14644~~

This part of ISO
14644 specifies
requirements for
periodic testing of a
cleanroom or clean
zone to prove its
continued
compliance with
ISO 14644-1 for

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the designated classification of airborne particulate cleanliness. These requirements invoke the test described in ISO 14644-1 for classification of a cleanroom or clean zone.

~~ISO 14644-2 E~~

ISO 14644,
Page 36/78

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Cleanrooms and associated controlled environments - Part 3: Test Methods, is referenced in many of the ISO/TC 209 Standards. Scope of ISO 14644-3 This part of ISO 14644 specifies test methods for designated classification of

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airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones.

~~ISO Standard
14644-3, Test
Methods~~
DIN EN ISO
14644-2. February
2001 Cleanrooms
and associated

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controlled
environments - Part
2: Specifications for
testing and
monitoring to prove
continued
compliance with
ISO 14644-1 (ISO
14644-2:2000);
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monitoring methods
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Classification and
Routine

Environmental
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Particle Sampling
Methods (2019)~~

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classification and
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~~ISO 14644 2 {Part
1}~~ Cleanroom
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2015 \u0026

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CLEAN ROOMS

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~~to Clean Rooms~~

Basic Introduction

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Monitoring Suiting
up to enter our
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~~Valtria Nueva ISO~~
~~14644 1 2 2015~~
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~~Industria~~
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LaboGene's new
class 2 safety
cabinets - low noise
& energy

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Regulatory

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~~14644-1~~

ISO 14644-1:2015
does not provide for
classification of
particle populations
that are outside the
specified lower
threshold particle-
size range, 0,1 μm
to 5 μm .

Concentrations of
ultrafine particles
(particles smaller
than 0,1 μm) will

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be addressed in a separate standard to specify air cleanliness by nano-scale particles.

~~ISO — ISO
14644 1:2015 —
Cleanrooms and
associated ...~~

Concentrations of ultrafine particles (particles smaller than 0,1 μm) are

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addressed in ISO 14644-12, which specifies air cleanliness by nano-scale particles, while an M descriptor (see Annex C) may be used to quantify populations of macroparticles (particles larger than 5 μm).

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~~DIN EN ISO
14644-1:2016
Cleanrooms and
associated ...~~

din en iso 8536-4 :
2013 : infusion
equipment for
medical use - part
4: infusion sets for
single use, gravity
feed (iso
8536-4:2010 + amd
1:2013) din en iso
14644-3 : 2006 :

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cleanrooms and
associated
controlled
environments - part
3: test methods

~~DIN EN ISO
14644-1 : 2016 |
CLEANROOMS
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~~...~~

DIN EN ISO
14644-1
Cleanrooms and

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associated
controlled
environments - Part
1: Classification of
air cleanliness by
particle
concentration (ISO
14644-1:2015)
standard by DIN-
adopted European-
adopted ISO
Standard,
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cleanrooms and

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environments - part

1: classification of

air cleanliness by

particle

concentration (iso

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14644-1:2015)
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~~DIN EN ISO
14644-1 E : 2016 |
CLEANROOMS
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...

This part of ISO
14644 does not
provide for
classification of
particle populations
that are outside the

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specified lower threshold particle-size range, 0,1 μm to 5 μm .

Concentrations of ultrafine particles (particles smaller than 0,1 μm) will be addressed in a separate standard to specify air cleanliness by nano-scale particles.

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~~Cleanrooms and
associated
controlled
environments~~

No assumptions are made regarding the distribution of the actual particle counts over the area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying

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assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling to be used in rooms where the particle counts vary in a more complex manner.

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~~ISO
14644-1:2015(en),
Cleanrooms and
associated
controlled ...~~

Comparison of
cleanroom classes
according to DIN
EN ISO 14644-1
and US FED 209D
For the production
of sterile drugs
(pharmaceuticals),

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four clean room classes according to the EU-GMP guideline Annex 1 normally apply with regard to the areas. The following table contains the classification according to the particles contained in the air.

~~Reinraumklassen~~

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~~ISO 14644-1 GMP-
Klassen
(Pharmazie) | IAB~~

...

After ANSI and IEST petitioned to ISO for new standards, the first document of ISO 14644 was published in 1999, ISO 14644-1. In 2000, ISO 14644-2 was published,

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which began the process of FED-STD-209E being canceled. On November 29, 2001, the document was canceled and superseded by ISO 14644-1 and ISO 14644-2. ISO 14644 is now composed of

~~ISO 14644~~

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~~Wikipedia~~

What is

ISO14644-1? •

ISO 14644-1

specifies classes of

air cleanliness in

terms of the

number of particles

expressed as a

concentration in air

volume. • It also

specifies the

standard method of

testing to determine

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cleanliness class,
including selection
of sampling
locations.

ISO14644-1 is one
of the most used
standards in
Pharma and

~~Understanding ISO
14644-1/2:2015
and Becoming
Compliant~~

ISO 14644-15:2017

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provides requirements and guidelines for assessing the chemical airborne cleanliness of equipment and materials which are foreseen to be used in cleanrooms and associated controlled environments which are linked to the

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ISO standard for
cleanliness classes
by chemical
concentration (see
ISO 14644 8).

~~ISO ISO
14644 15:2017
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DIN EN ISO
14644-14 -
Cleanrooms and
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14: Assessment of
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Published by DIN
on January 1, 2017

~~DIN EN ISO
14644-1~~

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1: Classification of

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The developed standard DIN EN ISO 14644 covers the planning and the
Page 70/78

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operation as well as the monitoring of the cleanrooms.

The ISO 14644 directive family is divided into various parts for this purpose. Whereby parts 1 and 2 cover the entire cleanroom. The following table gives you an insight into the first 5 parts

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of DIN EN ISO
14644.

~~ISO 14644 and VDI
2083: connections
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ISO 14644-1:2015
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classification of
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size range, 0,1 μm

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to 5 μm .

Concentrations of ultrafine particles (particles smaller than 0,1 μm) will be addressed in a separate standard to specify air cleanliness by nano-scale particles.

~~NUEVA VERSIÓN
DE LA NORMA ISO
14644~~

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This part of ISO 14644 specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness. These requirements

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invoke the test described in ISO 14644-1 for classification of a cleanroom or clean zone.

~~ISO 14644-2 E~~
ISO 14644,
Cleanrooms and
associated
controlled
environments - Part
3: Test Methods, is

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referenced in many of the ISO/TC 209 Standards. Scope of ISO 14644-3 This part of ISO 14644 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and

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clean zones.

~~ISO Standard
14644-3, Test
Methods~~
DIN EN ISO
14644-2. February
2001 Cleanrooms
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controlled
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2: Specifications for
testing and
monitoring to prove

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compliance with
ISO 14644-1 (ISO
14644-2:2000);
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