Providence Enterprise
Full-Service Global Contract Manufacturing

From a 1-Hour to a 3-Minute Read:

FDA'S GUIDELINES FOR MACHINE LEARNING IN MEDICAL DEVICES

The Abridged Version

Late last year, the FDA released its list of ten guiding principles for good machine learning practice (GLMP) in medical devices.

That's the good news. Right?

Good News, Bad News, **Good News...**

Bad News:

The guidelines are still a federal document. You know, the type we all struggle through only when we have copious amounts of time, patience, and caffeine.

Good News:

It is much, much shorter than documents past, perhaps to appeal tl;dr ("too long; didn't read") generations. We imagine that the brief was something like: "All ten guidelines must fit on one page". And they did it.

Bad News:

They cheated.

Short... **by FDA Standards**

The font has been shrunk to cram over 700 words onto a single page, leaving no room for an introduction. Leaping through the obvious loophole ("You never said the intro had to fit on the same page!") readers have been gifted an additional 750-word preamble.

The first page does have a nifty table outlining the guiding principles in shorter form. Unfortunately, to make that fit they compressed the font to 5 or 6pts, barely readable to the squinting eye.

Fun fact:

90% — For your audiences to understand at least 90% of what you read, sentences should be kept to **14 words or less.**

10% — Once a sentence hits **43 words or more,** comprehension drops to less than 10%.

In a bow to irony, the principle that advocates clarity in messaging begins with a 65-word sentence.

So here is our gift to you (and to the FDA):

FDA's guiding principles **in 14 words or less**

Gather your experts

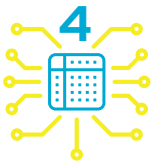
Assemble a multi-disciplinary team to ensure device safety and effectiveness.

Take care when implementing software

Observe good engineering and cybersecurity practices.

Test for intended users

Use test data and clinical study participants who represent your target population.



Keep datasets separate

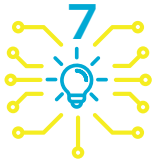
Prepare independent datasets for training and testing/validation.

Perfect your reference standards

Employ best practices to attain the most useful, clinically relevant reference datasets.

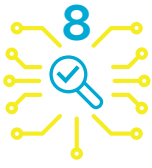
Make data applicable

Use ML findings to create a safe and effective model design.



Cover all bases

Supplement ML findings with human experience and insight.



Test for the real world

Verify that the device performs as expected for intended patients and environments.

9 Tell users what they need to know

Provide easy access to clear information, instructions, and updates.

10 Monitor devices in real world

Continue gathering performance data on deployed devices.

When clarity **matters**

And we get it. It's the great paradox of having to be both concise and precise that governments struggle with and lawyers flat out ignore.

However, in medical device development and manufacture, every miscommunication can snowball into a big, costly problem. Therefore we take every step to ensure that our clients clearly understand every conversation, document and report.

Find the FDA's full document:
Good Machine Learning Practice for Medical Device Development: Guiding Principles

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to learn more

About Providence Enterprise

Providence Enterprise is a Hong Kong contract manufacturer with manufacturing in China & Vietnam. We specialize in electronics, electro-mechanical assemblies and high-volume disposables. We are FDA registered and ISO 13485, ISO 14971, ISO 14001, ISO 27001, IATF 16949, and ISO 45001 certified. Our capabilities include fabricating tooling for silicone rubber and injection molded plastics, clean room injection molding, electronics, clean room assembly, and sterilization.

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