FCC-FDA
JOINT WORKSHOP ON
MEDICAL TECHNOLOGY INNOVATION
AND
WIRELESS TEST BEDS
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Session One
Defining the Need for and Scope of Wireless Medical Device Test Beds

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What is the problem being solved?

- Quantifying the operational reliability of the wireless functionality of medical devices in electromagnetic environments.
- Predicting the potential impact of new wireless technologies on those already deployed and in use.
- Gaining insight into the experience deploying and using new wireless technologies in healthcare environments.

What is the test bed?

- A **specific place** and organization that performs testing.
- A **function** that transfers and translates information from diverse but mutually impacting fields with the purpose of improving healthcare delivery.
- A **process** for connecting field experience to medical device design decisions with the purpose of improving reliability.

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Required relationships the test bed must address

and

accurately communicate to:

Correlation to the RF environments devices will be operating in.

Since those environments continually change, this is an ongoing challenge. But the tests need to predict field performance. Ideally the test bed can be forward looking and somewhat predictive of RF environments, wherever clear trends can be observed.

Effectively bridge from research to compliance testing.

Compliance testing must be efficient so as to be affordable for individual products. This implies that a sparse matrix is testing representing the corner cases of all the variations that will exist in the field situation. Research identifies the corner cases and how a small amount of testing can predict a much more complex set of configurations and operating states.

The test bed must be applicable to initial evaluation AND to both component and product planning.

The tests must be transferable into product development teams. The critical decisions about a design are made years before a product is ready for testing. Often the critical decisions are made by component and chip designers, who don't even know that their device will be used in a medical product.

Test results are viewed on band and protocol independent scales.

A lot is decided once an operating band and RF protocol are selected. The impact of band and protocol selection choices should be clearly observed.

The test bed should contemplate both normal/Gaussian distributed events and non-Gaussian events, particularly predictable low-probability, high-impact events.

Normally distributed events can be understand by sampling current environments and computing the probability distributions. This is not true of low probability, high impact events.

The test bed should include consideration for all people and adaptive devices commonly used by people with disabilities.

Healthcare delivery is needed by the full population, including people with temporary or permanent disabilities. Potential interactions with commonly used adaptive devices needs to be included. Hearing aids are one example.