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**TOX IVOS: Workhorse of the
Laboratory**

As Associate Director, Developmental and Reproductive Toxicology, at WIL Research, a contract research organization engaged in non-clinical safety assessment, Dr. Donald Stump conducts a wide range of studies. These research projects focus on fertility, embryo-fetal development, and postnatal development in several species - primarily rat, mouse, rabbit and dog.

Dr. Stump points out, "the IVOS has been very dependable and allowed us to more efficiently collect study data. We also have been able to measure sperm parameters that we would be unable to assess using manual procedures. **The IVOS has been a real workhorse in our laboratory.**"

The TOX IVOS' ability to review stored images is very useful from a quality control standpoint. Dr. Stump says, "The IVOS is one of the few instruments that we have been able to make compliant with the FDA 21CFR Part 11 requirement for electronic data records." This is important because it speeds up the FDA application process.

Stump points out that the TOX IVOS' flexibility allows "us to assay sperm from several species. This has been very helpful to us from a marketing standpoint... combining the expertise of the scientific staff at WIL along with the IVOS has allowed us to capture a large number of projects designed to assess male fertility."

Dr. Stump remains a loyal customer because he has found that Hamilton Thorne continues to make improvements to the TOX IVOS - including upgrading the operating system and making software enhancements.

A big factor in Dr. Stump's decision to purchase the TOX IVOS was Hamilton Thorne's customer service record. He says, "It has turned out to be a very good working relationship. Hamilton Thorne has always been very helpful in resolving any problems."

FDA 21 CFR Part 11 Requirements

- Validation
- Ability to generate accurate and complete copies of records
- Archival protection of records
- Use of computer-generated, time-stamped audit trails
- Use of appropriate controls over systems documentation

[Our thanks to Emily Baillie for recommending Dr. Stump for the Customer Profile.]

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