

# SES Medical Technologies

ISO 9001:2008 & ISO 13485:2003 Certified

## Real Time Aging (aka Shelf Life Testing)

### Real Time Aging of Medical Products & Devices In an ISO 9001 and ISO 13485 Lab

#### Shelf Life Must Meet Labeling Claim

The U.S. FDA recommends medical product and device manufacturers to develop a written testing program to prove that the products they manufacture have shelf lives that meet claimed expiration labeling. The European Medical Device Directive (MDD) requires that all sterile medical devices must have an expiration date. Evidence of shelf life must be shown. Real Time Aging involves storage under controlled conditions that are representative of the expected real-life storage conditions. Requirements for these tests include the need to demonstrate acceptable product performance including the effects of raw material and processing variation, which necessitates the testing of larger quantities of production product.

#### Real Time & Accelerated Life Testing Are Not the Same

Unlike accelerated methods where temperature, humidity, stress level, chemical concentration, etc. are often used to accelerate possible degradation mechanisms to evaluate failure modes in a development setting, Real Time Aging is much more narrowly focused. Real Time Aging is maintained at realistic storage conditions for a period of time representative of the actual claimed shelf life of the product.

Typical Real Time durations are in the range of 2-5 years. The challenge with these tests is not the methods of thoughtful



acceleration of time but rather the patient marking of time. The challenge is to ensure a stable storage environment ... at reasonable cost.

#### SES Has the Facility...and the Patience

Recognizing that many companies do not want to devote staff, physical space or be burdened by the myriad of other maintenance expenses associated with a testing environment that, by definition are not integral to the development of innovative products or devices, they often look to outside testing organizations to provide Real Time facilities. Stress Engineering Services (SES) is one such organization.

Careful thought has been given to the planning of this facility, including:

- Back-up power generation to ensure uninterrupted aging
- Continuous remote monitoring of environmental conditions
- Annual calibration and preventive maintenance
- Internal racking for improved airflow and sampling ease



### Value Added Services ... All In One Location

SES has experienced technician and engineering staff that can support your chamber management and sampling plan. We can execute most mechanical and material-related testing in our medical device testing laboratory.

### ISO 13485 and ISO 9001 Certified

SES's Mason, Ohio facility is a full-service ISO 9001 and ISO 13485 certified testing laboratory devoted to all aspects of medical device design support and testing. These certifications verify that we have effective product design, development and documentation processes in place which empower and enable us to provide safe and effective results. The laboratory includes both mechanical and materials testing facilities, as well as polymer identification and characterization equipment.

Laboratory Oven Specifications						
Name/Description	Model #	Quantity	Size	Temperature Range	Humidity	Other Unique Capabilities
CSZ Environmental Chambers	ZPH-32-3.5-3.5-SC/AC	1	32 ft <sup>3</sup> (38" cube)	-70°C to 19°C	10% to 98% RH	programmable temps and humidity cycles
CSZ Environmental Chambers	ZPH-32-3.5-3.5-SC/AC	2	32 ft <sup>3</sup> (38" cube)	-45°C to 190°C	5% to 98% RH	programmable temps and humidity cycles
CSZ Environmental Chambers	ZPH-32-1.5-H/AC	3	32 ft <sup>3</sup> (38" cube)	-34°C to 190°C	10% to 98% RH	programmable temps and humidity cycles
CSZ Environmental Chambers	ZPH-16-1.5-H/AC	3	16 ft <sup>3</sup> (30" cube)	-34°C to 190°C	10% to 98% RH	programmable temps and humidity cycles
Thermatron	SE 2000-6-6	2	64 ft <sup>3</sup> (48" cube)	-70°C to 190°C	N/A	programmable temps
Conditioning Ovens	BCO	6	8 ft <sup>3</sup>	15°C to 85°C	N/A	designed for long-term testing
Walk-in Environmental Chamber	Environtronics	1	500 ft <sup>3</sup>	-20°C to 85°C	20% to 95%	
Stability Chambers	SESV1	1	300 ft <sup>3</sup>	5°C to 40°C	20% to 93%	temp control +/- .2°C / RH control +/- .5% custom designed for lithium ion battery testing
Stability Chambers	SESV2	4	600 ft <sup>3</sup>	5°C to 40°C	20% to 93%	temp control +/- .2°C / RH control +/- .5%
Stability Chambers	SESV3	1	1200 ft <sup>3</sup>	5°C to 40°C	20% to 93%	temp control +/- .2°C / RH control +/- .5%

## For All Your Real Time Aging Needs

Call SES Today at 513-336-6701

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