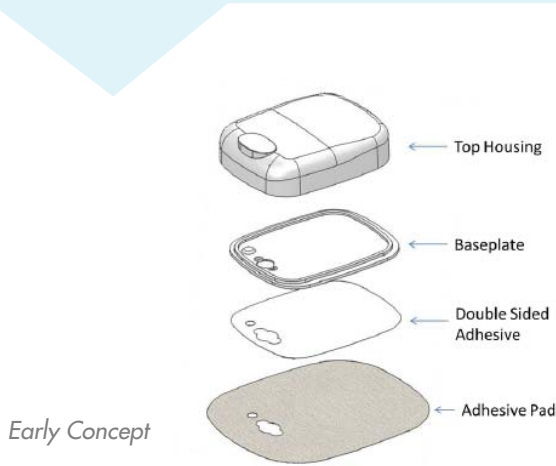


DRUG DELIVERY CASE STUDIES

ISO 9001 & 13485 CERTIFIED

WEARABLE DRUG DELIVERY SYSTEM RELIABILITY PLANNING

SES assisted a client with the development of a reliability plan prior to concept generation. SES provided an assessment of the existing plan and led execution of activities to remedy gaps prior to concept development. This planning included sample sizes necessary for reliability predictions and an audit to ensure that all requirements were adequately addressed through testing. The deliverable of this initial phase was the reliability plan. Later in the process, SES was re-engaged to provide follow-up evaluation of reliability plan execution and interpretation of test results as well as design recommendations for areas of concern.

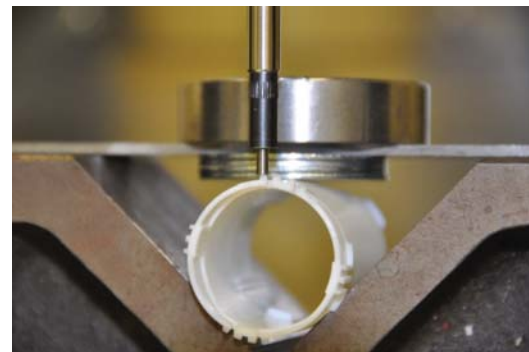


max failures	target cycles	test cycles	# units to demo 99% reliability	# units to demo 95% reliability	# units to demo 90% reliability	# units to demo 80% reliability	# units to demo 70% reliability
0	1	1	299	59	29	14	9
1	1	1	473	93	46	22	14
2	1	1	628	124	61	30	19
3	1	1	773	153	76	37	24
4	1	1	913	181	89	44	28

Test matrix for a reliability plan

INJECTION PEN DESIGN FOR MANUFACTURABILITY

SES assisted with the design of an injection pen. The device used cantilever arms with friction pads to transfer a portion of the actuation force. SES designed the arms and conducted tolerance analyses to determine expected range of positions and thicknesses. Next, finite element analysis was used to predict normal forces across the expected range of dimensional variability. Friction tests were conducted to measure the range of drag forces as a function of normal force. Deliverable was a design capable of meeting force target window across the range of expected variation. Finally, the pilot parts were tested to ensure the assembly would be capable.

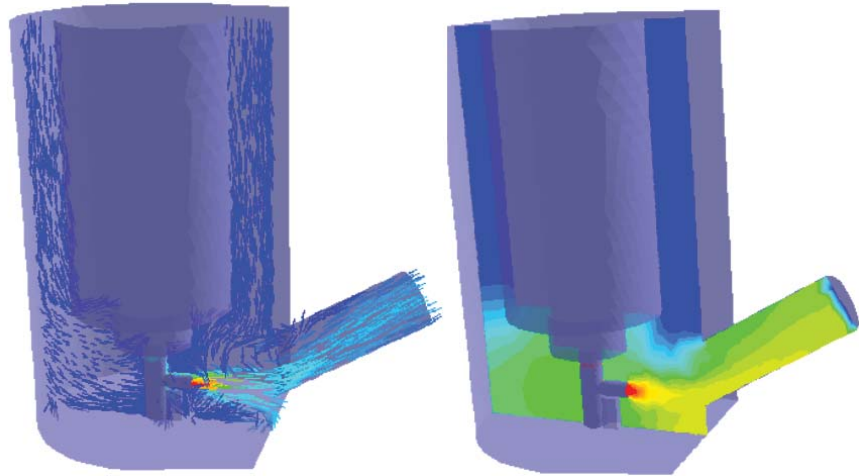


Pilot parts under test



INHALER DESIGN & SIMULATION

SES improved the design of an inhaler to address dispensing and make a more uniform droplet formation. SES used computational fluid dynamics (CFD) to simulate and analyze air entrainment, drug dispersion and mixing. A number of 'what-if' scenarios evaluated and design optimized prior to prototyping.



Computational Fluid Dynamics is used to simulate and analyze air entrainment



TEST FIXTURE & EQUIPMENT DEVELOPMENT

SES designed, built, qualified, and delivered a custom test machine. The machine was used to check a drug delivery pens dose accuracy and cycle time as part of quality testing for lot certification.



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