Bluepharma - Indústria Farmacêutica S.A.

PROBLEM STATEMENT

A legal obligation for the Pharmaceutical Industry is to monitor the quality of their products during its life cycle.
The activity of development new pharmaceutical products (generics) leads to a high number of batches to test to accomplish with an ICH Stability Program and the timelines are critical.
The problem is how to manage and schedule the tests of several projects that run at the same time, to avoid delays in the answers.

The ICH stability plan frequently assumes the following aspect:

Months **Storage conditions**	**3**	**6**	**9**	**12**	**18**	**24**	**36**
Long-term: 25ºC/60% R.H.	x	x	x	m	x	m	m
Intermediate: 30ºC/65% R.H.[a)]	x	x	x	m	x	m	
Accelerated: 40ºC/75% R.H.	x	m					

Legend: x: without microbiology; **m:** full test acc. to shelf life specification, including Microbiology.
[a)] Only tested if "significant change" (according to ICH Q1A) occurs at accelerated condition.

This kind of table is applied to each packaging system proposed
It is applied to 3 pilot/industrial batches per strength.

In the last year it represents a universe over then 1000 batches to test.