

**FIGURE I**

The elements that make up a computerised system (ref. T. Stokes).

Illustrations by Tony Moore.

Must it all be validated?

Not every computerised system needs to be validated, or validated to the same extent (although there are few areas that would not benefit from validation). However, when it comes to GxP-regulated systems, the authorities clearly express their expectations for

- company management to be in control
- systems to be reliable
- data integrity to be acknowledged
- quality to be auditable.

Validation provides documented evidence that the performance of the computerised system will be consistent and in