use in cleaning calculations. The committee secretary shall make such medical information available to Operations Sites and R&D functions on request. Where requests are made for product information not currently available, the committee secretary shall obtain the relevant information with the assistance of other committee members. Documented statements, signed by appropriate company medical experts, supporting the medical information shall be available from committee to support Regulatory Inspection process.

Committee should employ the same medical information used to determine the OEL, where this available, to ensure consistency between Occupational Safety and GMP approaches to patient and operator safety.

Requests for advice should be made in writing including as much information as Possible. Requests should be made to the secretary of the committee and should identify the specific issue or information required. Any relevant information on proposed manufacturing process or sitting should be included where available, as should any relevant clinical, pre-clinical safety or toxicity data where available.

Committee should maintain copy records of any recommendations provided. Signed copies of written advice shall be provided to the requesting site or function, who are responsible for maintenance of the original signed record.

After evaluation, the output from the committee may include: recommendations on the sitting of compounds, recommendations concerning safety factors applicable for ACQ calculation, a quantitative ACQ value to which cleaning validation should be performed, additional testing or validation requirements, and/or a recommendation regarding equipment or plant dedication, where necessary.

On completion of the evaluation, committee secretary shall issue a written evaluation statement to the person requesting the information.

5.3 Contents of an evaluation request

Supporting Information (where available and as appropriate to the request):
Details of any ACQ calculations including therapeutic dose information (MED, NED, MTD, or MDD) and safety factors used to calculate the ACQ
Other Clinical and/or safety (toxicity) data
Quantities involved (including smallest batch size if available)
Proposed siting location
Manufacturing process
Synthetic schemes (API or intermediates)
OEL data
Cleaning Validation, or other Cleaning data

