

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10161

Richlyn Labs.

Major Deficiencies

1. Staffing Deficiency

Failure of one supervisor to have technical qualifications for the necessary supervisory functions. Another supervisor who is a chemist with pharmaceutical experience cannot allocate adequate time for supervision between operations of Richlyn and another affiliated company.

Inadequate laboratory supervision and technical review by chemist in charge.

Release of a batch which should have been rejected by the chief chemist based on test data indicates violation of quality assurance.

2. Laboratory Control Deficiency.

Incomplete and improper testing of raw material.

Failure to reject material in non-compliance with applicable specifications.

3. Production Control Deficiency

Absence of specific instructions on the Master Formula and production records for the manufacture of each item. Personnel manufacture in accordance with their experience rather than with delineated procedures. This may create non-uniformity of finished product.

Failure to record total granulation weight on batch production record in accordance with company requirements, thus including checks of theoretical yield against actual yield.

Absence of temperature recorder in drying oven to verify temperature used in drying granulation. Temperatures of all ovens varied although temperature control settings were the same.

4. Poor Housekeeping

Regular cleaning failed to remove drug residues or dirt accumulations on drying racks, walls, floors, containers, tableting machine and filter in air system supply heat to drying ovens, thus resulting in the possibility of cross contamination of product.

Exhaust fan in weighing room not screened, thus creating possibility of entrance of flies and other flying insects.