

# Toxicology *focus*

TAKE ADVANTAGE OF OUR EXPERTISE AND LET US BE YOUR RESEARCH PARTNER.

## Grants for research from the Bill and Melinda Gates Foundation

The Bill & Melinda Gates Foundation has announced 78 grants of \$100,000 each to be based at universities, research institutes and charities. Grants include the development of a low-cost cell phone microscope to diagnose malaria, study of the strategic placement of insect-eating plants to reduce insect-borne diseases, investigation of nanoparticles to release vaccines when they come in contact with human sweat and the use of ultrasound as a temporary form of male contraception. The grants support research across 18 countries and six continents.



## Big pharma still not confident

More than three quarters of the executives surveyed said they are worried about the European Commission's ongoing investigation into patent settlements between branded drug makers and generics firms. The probe into so-called "pay for delay" deals will result in "serious fines," say the executives.

Executives also believe that the reduction in drug margins imposed by US healthcare reform will be offset by increased sales. Eighty two percent of pharma executives predict that pharma companies cannot replenish their pipelines internally. Some 68 percent are expecting many deals over the next two years as big pharma teams up with biotechnology companies to acquire new compounds.



# The role of the toxicological pathology in Drug Safety Evaluation.....from the glass slide to human safety

Your toxicological pathologist should be able to consult on gross pathology (necropsy observations), histopathology (microscopic observations), haematology, clinical chemistry, urinalysis, electron microscopy and immunohistochemistry. Pathology plays a critical role in safety assessment of foods, drugs, chemicals, and medical devices. Accurate description and interpretation of pathology data is crucial for safety assessment.

Your toxicological pathologist should be able to identify potential compound-related effects and separate normal biological variation and spontaneous disease from compound-induced changes. All alterations should be recorded and graded. Your toxicological pathologist should have a veterinary medical training as well as additional training, experience, and expertise in diagnostic pathology, laboratory animal pathology, research techniques, toxicology testing and Good Laboratory Practices (GLP).

Your pathologist should be able to tell you whether compound X has caused any effects and if so, what they mean to safety in humans. They should ensure that important findings are understood and should work with the toxicologist and regulators to ensure appropriate evaluation of toxicity and risk of a new drug.

Pathological lesions in treated animals show a 71% correlation with human adverse effects when similar organ systems are affected in both rodent and non-rodent species, 63% correlation when only the non-rodent animals are affected and 43% correlation when only the rodent species are affected (Olson H, et al. 2000. Reg Toxicol Pharmacol. 32:56-67).

Pathological lesions in animal studies show the greatest correlation in predicting human adverse effects in the haematological system, the gastrointestinal system and the cardiovascular system. Pathological lesions in treated animals are least predictive for effects on skin and hepatobiliary systems.



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