ISSN: 2583-9365

Short communication

Laboratory animal science and experimentation in India : Review of the last decade

Qadri S.S.Y.H.

He completed post graduation in Veterinary Pathology in 1987 from A.P. Agricultural University. He is recipient of gold medal in Veterinary Pathology (1987), a Young Scientist award (1995) and Mahaveera Vishwa Sadhbhavna Puraskar for animal welfare (1999). Currently he is working as Senior Scientist (Veterinary Pathologist) in the Pathology Division at the National Institute of Nutrition (ICMR), Ministry of Health and Family Welfare, Government of India. He worked as an Advisor (Expert Consultant) to the CPCSEA for three years on deputation. He is a Certificate holder in Lab Animal Science from Utrecht University, Netherlands and FELASA level 'C' from Europe. He is a Board Certified Veterinary Pathologist in India (Diplomate ICVP). He is the founder of SPCA and PFA at Hyderabad and Secunderabad. He is also the founder and present Secretary General of the Laboratory Animal Scientist's Association of India. He has vast experience in animal experimentation especially dogs, primates and other smaller laboratory rodents and has completed over a hundred preclinical toxicology projects and reviewed histopathology slides from toxicology studies in more than 40 projects..

Corresponding author :
S.S.Y.H. Qadri, Dept. of Pathology
National Institute of Nutrition, Hyderabad 500 007
Phone : 09849518510, email : ssyhq@yahoo.com

Qadri S.S.Y.H.
National Institute of Nutrition
Hyderabad 500007, India

Key words : laboratory animals, experimentation, india

Ever since the revival of the Prevention of Cruelty to Animals Act (1960)in 1998, the law was amended and implemented with renewed vigor, the animal welfare and laboratory animal experimentation has seen a major change. The strict implementation of the law during the early part of the decade led to the spilling of skeletons from cupboards of some very well known and established institutions in India. The implementation of the law not only revealed the lack of basic facilities and poor and unhygienic conditions in animal facilities, it also revealed the laid back attitude of those who were responsible. The increase in awareness that was achieved through the animal welfare movement in India was enormous. It has led to the improvement of laboratory animal facilities in several institutions and the commissioning and constitution of Institutional Animal Ethics Committees (IAEC) in all the CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals), Animal Welfare Division, Ministry of Environment and Forests, Government of India, registered organizations. The IAEC is in turn playing a major role in improving the welfare of the animals used for experiments. Nevertheless, the improvement of animal facilities in the Pharmaceutical industry and the Contract Research Organizations (CRO) to this day are driven more by the need to attract and capture business than a true change in the heart for the welfare of animals. The race for acquiring Good Laboratory Practices and Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) accreditation in the private industry, and the contrasting laid back attitude in the Government sector as was evident before 1998 is a clear indication of this fact. It may also be considered here that the threat of the law and negative public opinion has played a significant effect on the Government Institutions and several of them did release funds and have improved the animal facilities in their respective organizations.

Till date, approximately 1400 organizations have registered with the CPCSEA. This includes a large number of organizations from the pharmaceutical industry, CRO's, medical, pharmacy and university colleges in the private sector and biomedical research institutions, medical, veterinary, pharmacy and university colleges in the Government sector. Majority of these facilities are very primitive and consist of two to few rooms. Some have installed air-conditioners whereas others have only fans or air coolers. Several medical and pharmacy colleges have 2-3 room animal facilities with concrete or stone shelves on the walls that are used for placing the cages. This design was in vogue during the 1950's and 60's. The authorities probably had no idea about the concept of clean and dirty corridors. Most facilities do not have proper electricity and water. The staff is not trained and in many of these institutions, the animals to this day are fed some bread, soaked horse gram in case of rats and mice and cabbage and carrots to rabbits.

About half a dozen organizations in the private sector obtained AAALAC accreditation, while some of these have also achieved GLP accreditation from Netherlands or Germany or India. Unfortunately, most of these accreditation bodies concentrate more on the facilities and the protocols that pertain to animal welfare giving very little importance to the quality (health and genetics) of the animals. This has led to a situation where a majority of registered organizations prefer to procure cheaper animals and feeds of inferior quality for their research. The regulatory authorities most often are either not aware of these issues or are not much concerned about it.

The availability of human resources is another important factor that is a major impediment in the proper growth of this sector. There is a huge gap in the availability of qualified and trained technical staff to work in the laboratory animal facilities compared to the number of animal facilities mushrooming in this country. The problem is compounded by the unavailability of veterinarians. A majority of animal facilities in the Government sector are headed by either the heads of the pharmacology departments or by the zoology departments in the colleges which is more often an additional charge of the facility. The Act of the Parliament of India, the Veterinary Council of India Act 1984 and its amendment of 1992 authorizes only qualified and registered veterinarians to breed and experiment on animals. The CPCSEA rules under the PCA Act 1960, Chapter IV, have also laid the rules for laboratory animal breeding and experimentation, and the qualifications and expertise of those who plan to conduct the experiments. However, there is lot of ambiguity in the law and needs clarification. The ambiguity in the law has also led to a situation where any body, is permitted to do animal experiments whether he/she is qualified or not. This has led to a situation where the intention and purpose for which the CPCSEA has been formed is at stake.

Majority of the organizations have obtained CPCSEA permission to breed as well as experiment on animals. Unfortunately, most of the facilities do not have the capacity nor have the trained staff to breed quality animals for research. A majority of these organizations are breeding animals randomly. Invariably, most of them do not have the means to phenotypically differentiate between the strains nor are these facilities conducting any genetic monitoring to confirm the strain. This in turn reflects the present situation where the animals that are available from the suppliers do not have either the basic genotype data or the suppliers aware of the microbial, viral load or even the latent infections prevalent in these animals. Background pathology of most of such animals is very poor with a majority of animals showing respiratory infections, abscesses in lungs, kidneys, livers, parasitic loads, degeneration and necrosis in the liver, interstitial nephritis etc., besides spontaneously developed tumors. Literature surveys reveal that most of the pathogens causing diseases in animals are known to interfere with the research results and in most cases invalidate the data. Therefore, the quality of the animals that are available for research gives a clear indication of the quality of the research carried out in most institutions. These issues do not come either under the purview of the CPCSEA nor under the AAALAC accreditation system. This is compounded by the fact that most scientists and administrators alike would like to see the other way when such issues are raised as quality animals and feed costs more.

Off late, it has become a fashion to say that one is following the 3 R's principle of Russel and Bursch. It is unfortunate to note that many of the experimenters have not realized the scientific basis of these principles. No honest attempts are being made to find alternative to replace their animal experiments. It is quite common to observe in proceeding of the national conferences and symposia especially related to pharmacological sciences and toxicology that hundreds of experiments are being conducted by students for their dissertation work or for PhD thesis. Majority of these experiments are on testing some herbal drugs. The number of animal experiments conducted, are doubling every year and a majority of these experiments look redundant and could have been done using alternate methods. Again the regulatory authorities have been unsuccessful in controlling such experiments. There is an urgent need for educating the concerned authorities to encourage and educate the students to use alternatives and avoid duplication or redundant research using poor quality animals.

The reduction in number of animals in each experiment is only possible when the quality of the animal facilities and also the animals are improved thus reducing the noise (variability) in the experiments, in turn reducing the number of animals required in each experiment as well as the number of experiments required to obtain the desired information. There are no minimum requirements/stipulations for organizations that breed and supply animals. The improvement in the quality of animals can be brought about only by permitting only those breeders and suppliers who breed healthy and genetically defined animals. This would necessitate the breeders and suppliers to regularly screen their animals for bacteria, viruses, parasites, mycoplasma, and the feed and water for their quality and content of toxins, contaminants such as heavy metals and pesticide residues. This would be the only way to even weed out profiteering and unscrupulous uncontrolled breeding of animals.

The refinement of techniques based on the 3 R's principles pertains to the design of experiments and the methodology adopted in conducting the experiments. This would require a comprehensive training of the experimenters on handling, restraint, dosing, sample collection, anesthesia, euthanasia etc. as well as the IAEC members who scrutinize the research proposals. Animals are being transported from north India to south India vice versa are under tremendous stress due to changes in climate conditions hence uniform handling techniques, environmental condition, feed and water is highly essential. All these factors have a tremendous impact on the stress status of the animal. These effects become confounding variables in an experiment. This can be avoided only when similar techniques and standards are followed all over the country.

With India joining the OECD and the opening of free trade between India and the European Union, would eventually lead to the outsourcing of regulatory toxicity data generation especially for REACH compliance. This would in turn lead to further mushrooming of animal facilities and breeding of laboratory animals on a large scale. The number of animal experiments would also increase in leaps and bounds. With the existing infrastructure and the quality standards, the future as far as the quality research and regulatory data generation is concerned it doesn't look very encouraging, unless drastic steps are taken by the authorities and scientists themselves in improving the situation.

Use of large animals especially beagles and non-human primates in India has already been curtailed to a large extent both by the inability of the scientific community to foresee the future and develop breeding facilities and by the unwritten laws of land where sentiments overrule scientific judgment. This is leading to a situation where, in the pharmaceutical sector a large number of studies are getting delayed as the necessary permission to conduct large animal experiments is not forthcoming. In the long run, this may become a major impediment for the growth of the pharmaceutical sector/drug development in India. The other effect of this that has been observed is the fast mushrooming of CRO's in neighboring countries especially the northern neighbor and the diversion of CRO business to these countries.

Hence, it is high time to all those who are concerned to highlight these issues in all the forum to bring about a change and an improvement in this sector. ■