



Editor's Note

Dear Members,

Welcome to another edition of INFAH CONNECT. At the outset, we would like to congratulate and welcome the new managing committee under the leadership of Dr D K Dey. We are confident that the team will lead INFAH towards newer avenues of excellence.

In the past few months, INFAH was engaged in major regulatory discussions including the meeting with CDSCO and MoHFW, 4th Regulators-Veterinary Vaccine Manufacturers meet, interface meeting with MOA and representation to MoHFW on 'Draft Pharmaceutical Policy'. We continue to represent the animal health industry on forums pertaining to AMR, with the most recent one being the EU-India Capacity building Initiative for Trade development. Our collaborative efforts with other Animal Healthcare associations continue with the recent meet held with AAHA to address common concerns. INFAH also participated in several industry gatherings like PVS-OIE Information seminar and 17th meeting of BIS.

INFAH continues its social initiatives with participation in events like World Egg Day and Pashu Arogya Mela. We are glad to share that the Indian Pharmacopoeia 2018 is now available with 14 additional Veterinary drug monographs, highlighting our endeavour to uplift Animal Health sector and contribute towards national growth. This edition also brings in-depth updates on the HR Subcommittee and Biological Subcommittee meetings. We are sure you all will cherish the glimpses of the 6th AGM meet covered in INFAH in-house section of the newsletter.

Also featured inside is news and happenings from across the Nation's Animal Health sector and prospective business strategies. We also give you a glimpse into some very interesting developments in the industry from across the globe. This edition also includes an exclusive article on the regulatory framework for approval of New Animal Drugs in the US. The issue also updates us on various circulars and announcements from the regulatory authorities.

Last but surely not least, we congratulate Dr D K Dey, President, INFAH for receiving the "Indian Poultry Review Award". We are proud to have him at the helm.

We hope you like this edition of INFAH CONNECT and look forward to your feedback and suggestions for the same.

With Regards,

Vijay Teng
Editor
INFAH CONNECT



From the President

"It is a matter of honour and responsibility to assume the position of President of an association as significant as INFAH. There are a lot of challenges ahead for the Indian Animal Healthcare Industry, which needs to be managed with utmost integrity. INFAH will work towards ensuring that the government policies shape up considering the ethos of the Indian Animal Health Industry. A strong and able Animal Healthcare Industry will keep the health of animals in the nation strong and secure.

INFAH was founded in 2012 and within short span of time; the progressive association has been able to make its presence felt both in national as well as international arena. I feel privileged to thank our past Presidents, Dr. Asim Banerjee, Mr. Satish Pasrija and Dr. Arun Atrey for their inspirational leadership and guidance. We are thankful to the wholehearted contribution of managing committee, subcommittees and member companies for dedicated and sincere efforts in supporting INFAH activities.

Indian Animal Healthcare Industry plays a significant role in safeguarding the animal husbandry in India. Poultry is the most organized sector in animal healthcare industry. India's formidable presence in Aqua culture also requires scientific approach through Aqua Healthcare management. Indian Dairy market is expected to double within a decade with rising economy. The animal health industry will be driven by increased adoption of innovative technologies for prevention & cure of diseases especially in companion animals. The high growth potential of the Industry needs to be leveraged and a sustainable and strong farming base will be a critical factor.

Now with greater responsibility, we are confident of creating a strong foundation of faith, trust and hope. INFAH's role will always be very crucial to deal with future challenges and to maintain favourable environment for sustainable growth by adopting best professional and ethical practices.

At INFAH we are gearing up to the challenges like

- Anti-Microbial Resistance (AMR)
- Market access of Indian Animal Health Companies to other Asian/ Global markets
- Regulatory concerns faced by Ayurveda segment
- Regulatory concerns of Feed supplement segment
- Post GST Challenges
- Human resource gap
- More organised approach towards Companion Animals and Aqua segments
- Creating a National level consensus on managing emerging and re-emerging disease.

I look forward to your whole hearted support. The united efforts have yielded valuable results, and always will!!!

Dr. D. K. Dey



IVRI and INFAH Jointly Organised 4th Regulators-Animal Vaccine Industry Interface



The 4th Annual Interface of Regulators and Animal Vaccine Industry was organised at Division of Standardization, Indian Veterinary Research Institute (IVRI), Izatnagar on 4th December' 2017. The interface was organised by Dr Ashok K Tiwari, Head, Division of Standardisation, IVRI and was presided by Dr R K Singh, Director and Vice Chancellor, IVRI and Dr Rishendra Verma, Professor Emeritus, ICAR. The interface was attended by 38 stakeholders of Animal Health Vaccine Industry and Regulatory bodies. The INFAH Biological Subcommittee under the stewardship of Dr D K Dey along with other representatives from the industry participated in the interface. The group also had representatives from the State Veterinary biologicals viz IAHV B (Thiruvanthapuram); Punjab Veterinary Vaccine Institute, Ludhiana; Institute of Veterinary Preventive Medicine, Ranipet and others. The group deliberated on the conventional, recombinant and autogenous vaccines and their prospects, regulations, constraints and its action plan. The interface had discussions on checklist and requirements for clearance of import vaccines and evaluation of vaccines supplied by Industry to government institutes. The group also discussed on the need to have monograph on autogenous vaccines to regulate the segment and CPCSEA issues of Veterinary biological testing.

INFAH Biological Subcommittee Meeting

The INFAH Biological Subcommittee met on 21st November 2017 at Hyderabad. The meeting was attended by Dr. Lalit Belwal, Dr. Nitin Bhatia, Dr. E. Shankariah, Dr. Sujit, Dr. D. J. Kalita, Dr. Prakash Reddy, Dr. Piruthivi Rajkumar,



Dr. Niraj Warke and chaired by Dr. D. K. Dey, Chairman, Biological Subcommittee.

During the meeting, it was re-emphasized that the Subcommittee will represent and work forward for the interest of both the biological manufacturers and importers. The Subcommittee deliberated on its agenda for meeting on 4th December 2017 with the Regulatory authorities at IVRI. The members agreed to emphasise on the need for H₅N₁ / H₉N₂ vaccines for the Indian poultry industry as well as the autogenous vaccines. The Subcommittee also discussed on the following points.

- i. Inclusion of monovalent vaccines only in the Indian Pharmacopeia as the multivalent vaccines and its evaluation varies.
- ii. Representation to be made for rationalising the custom duty and categorization of SPF eggs.
- iii. Proposing a training program for Industry by the regulatory authorities on adherence of regulatory norms for Veterinary Biologicals.
- iv. Representing the current constraints and action plan for Veterinary Biologicals with respect to both domestic and export business to the concerned regulatory authority.

EU-India Dialogue Seminar on the Use of Veterinary Medicine and AMR





Prudent use of antimicrobials in livestock production is one of the key strategies participating to the One Health Approach to Antimicrobial Resistance (AMR) being promoted by FAO, WHO and OIE. In this context, a two day dialogue seminar was organized by Export Council of India (EIC) and EU-India capacity building initiative for Trade Development (CITD) at The Grand hotel, New Delhi on 15-16th November 2017. The two days seminar was oriented to create an opportunity for gathering and exchanging information on respective legislations on registration and use of Veterinary Medicines. The seminar was also aimed to stimulate scientific and institutional cooperation between India and EU towards promoting practices, giving enhanced guarantees to authorities and consumers on the safety of animal production, whilst contributing to the implementation of strategies to combat antimicrobial resistance.

The inauguration session of the seminar was chaired by Mr Wojciech Dziworski and Mr Tomasz Kozlowski from the European Union; Dr A Ravi Shankar, Director General Drugs, Government of Andhra Pradesh; Dr S K Saxena, Director, EIC and Dr K Bangarurajan, Joint Drugs Controller, DCGI office. More than 150 participants attended the seminar representing the stakeholders of Indian Animal Health industry, Meat and Fisheries sector, Aquaculture sector along with representatives from CII, UK Science and Innovation network, Ministry of Agriculture and Farmers Welfare, EMA, FSSAI, MPEDA, NCDC, CDSCO etc. INFAH was represented during the seminar by Dr P G Phalke, Dr Shirish Nigam, Dr Nitin Bhatia and Dr Shyam Morada.

The technical sessions had deliberations on the registration and authorization of Veterinary medicines; use of Veterinary medicines and trade implications; monitoring and control of animal diseases; prevention and control of Anti-microbial resistance. During the deliberations, INFAH also presented the industry views on the highlighted concerns of Anti-microbial resistance in humans and its association with animal health sector. It was agreed that the prime culprit of AMR in humans is the over-use of antibiotics in human



patients and transfer of resistance in hospital premises. INFAH also highlighted its commitment to the Indian livestock sector and effective and prudent use of anti-microbials for control of infectious diseases in poultry sector.

INFAH participated in 17th Meeting of BIS for Animal Husbandry, Feeds and Equipments



The 17th meeting of Food & Agriculture Department, Bureau of Indian Standards for Animal Husbandry, Feeds and Equipments was held at Lal C. Verma Conference Hall, BIS Headquarters, New Delhi on 14th November' 2017 under the chairmanship of Dr R K Singh, Director and Vice Chancellor, Indian Veterinary Research Institute (IVRI), Izatnagar.

The meeting was attended by around 30 stakeholders associated with the Animal Husbandry sector. Dr P G Phalke, Dr Shirish Nigam, Dr Nitin Bhatia and Dr Shyam Morada attended the meeting on behalf of INFAH. Other participants included Department of Animal Husbandry, Dairying and Fisheries, IVRI, CSWRI, PETA, CARI, MDEF & CC, FAIPO, CSE, FAIPO, NDRI, AIPFMA, PFMA, Directorate of Poultry Research, NECC, All India Poultry breeders association and CDRI. The major points of discussion were specifications for pet foods, Indian standards on livestock feed ingredients, code of practices for raising the egg laying hens and prudent use of antibiotics.



INFAH Delegation Participates in CDSCO and MoHFW Meeting



Under the chairmanship of Dr G N Singh, Drug Controller General of India, a meeting of associations from the pharmaceutical sector was organised to discuss the measures to streamline the drug regulatory system as well as to ensure Quality, Safety & Efficacy of drugs manufactured in the country. The meeting was held at FDA Bhavan, CDSCO Headquarters on 14th November 2017. Apart from OPPI, IDMA, IPA and other associations of human pharma, INFAH represented the Animal Health pharmaceutical and biological sector. Dr Nitin Bhatia, Dr E Shankaraiah and Dr Niraj Warke represented INFAH. The discussions were oriented towards the GSR 429 (E) for stability studies of pharmaceuticals products and to synchronize Schedule M at par with WHO-GMP.



INFAH- AAHA Meeting



To continue the collaborative efforts with AAHA, the members of INFAH and AAHA had a close interaction recently at Mumbai on 3rd November 2017. The event was attended by Dr. D. K. Dey, Mr. Vijay Teng, Dr. Vijay Makhija, Dr. Arun Atrey, Mr. Satish Pasrija and Dr. P. G. Phalke from INFAH. Mr. Rajesh Agarwal, Dr. Yash Goyal, Mr. Milind Limaye, Mr. Ketan

Dhamanaskar and Dr. Sandeep Kharkhanis represented AAHA.

The meeting was scheduled to work closely with each other and address the common concerns which can subsequently be taken up with the concerned Regulatory authorities. Before proceeding with the agenda, Mr. Rajesh Agarwal gave a brief about AAHA and its activities across Asia. He emphasized that AAHA always works very closely with local associations and intends to work with the same spirit with INFAH as well in India.

Some of the important areas of discussion were harmonizing regulatory process, AMR, market access to different nations, data protection & confidentiality, veterinary pharmacopoeia and some of the import-export related matters.

The meeting ended on a very positive note with an intent to work closely for common goals and a larger benefit to the society.



INFAH participates in MOA's Meeting on Veterinary Vaccines



Ministry of Agriculture (MOA) organised an interface meeting on 31st October 2017 to assess the status of availability of Veterinary vaccines in India. The meeting was chaired by Mr Mihir Singh, IAS, Joint Secretary (Health), Department of Animal Husbandry, Dairying and Fisheries (DADF) and was participated by Ministry of Agriculture officials, INFAH members and representatives from State Biologicals. Amongst INFAH Managing Committee members, Dr Arun Atrey, Dr D K Dey and Dr Sandeep Karkhanis participated in the meeting along with INFAH biological subcommittee members and other industry professionals. The Ministry showed its proactiveness towards the industry and agreed for providing a platform for easing business options and bringing regulatory reforms. INFAH has finalized its draft representation and would be submitting to the concern ministry.

After the meeting, INFAH members also met Dr. Devendra Chaudhary, Secretary, DADF in relation to proposed joint farmer's meeting involving MOA and INFAH.

Participation in Pasu Arogya Mela in Patna

ICAR Research Complex for Eastern Region, Patna in collaboration with Bihar State Milk Co-operative Federation Ltd.(COMFED) organised "Pashu Arogya Mela 2017" at Village- Semuapur, Kesaria Block in East Champaran district of Bihar 28th and 29th October 2017.

Hon'ble Union Agriculture and Farmers Welfare Minister, Shri Radha Mohan Singh graced the occasion as Chief Guest during inaugural function of the event. More than 6000 farmers attended the mela in view of seeking technical



knowledge and to gain practical experience. Around 60 exhibition stalls related to animal health and production were displayed.

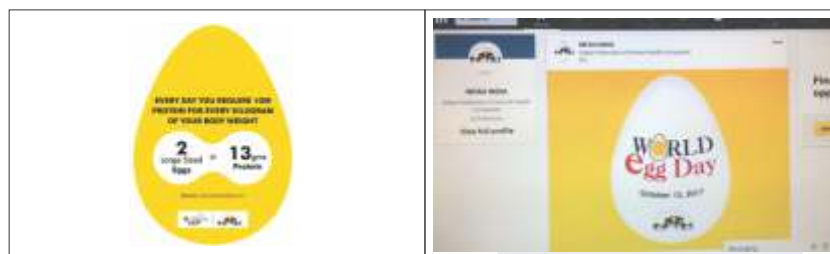
INFAH member companies also installed various stalls during the event and guided the farmers on importance of disease management, balanced nutrition and scientific farm activities.

Many major animal health institutes participated in the event i.e. ICAR-NDRI, Karnal, IVRI –Bareilly, ICAR-RCER, Patna, ICAR-CIRG, Makhdoom, ICAR-CIRB, Hisar, DRPCAU, Pusa, BASU, Patna, ICAR-CSWRI, Avikanagar, IGFRI, Jhansi, ICAR-CIFE, Mumbai, ICAR-Directorate of Poultry Research, Hyderabad, Central Animal Registration Schemes, Rohtak

under Ministry of Agriculture and Farmers Welfare, Institute of Animal Health, Baghpat, NDDDB, COMFED, Patna and Animal Husbandry Department, Govt. of Bihar.

World Egg Day 2017

INFAH took a small step towards the journey of achieving "Freedom from Malnutrition" by contributing in creating awareness on nutritional importance of Egg Protein on the occasion of World Egg Day on 13th October 2017.



Event at Girl's Orphanage, Mumbai



INFAH GMP & CSR Subcommittee in collaboration with AVI Mumbai, CLFMA of India, and PFI organized an awareness drive at Ma Niketan, an all-girls orphanage at Thane Mumbai. Girl students were educated on significance of protein consumption as per individual body weight by Dr Vijay Makhija, General Secretary, INFAH.



Dr P G Phalke, President, AVI Mumbai talked about significance of World Egg Day. Dr Ms Richa Bhargawa interacted with girl students on right nutrition, at right interval of time. She highlighted eggs as magical food, rich in Vitamins, Minerals and Protein. Sister Preetbala of Ma Niketan appreciated industry's efforts of organizing the awareness program for girl students. Girl students were offered boiled eggs after the presentation.

Dr Ganesh Ganghale, Dr Vishal Surve, Dr Pradip Naik played an important role in organizing and executing the event.

Event at Bombay Veterinary College



The world egg day was celebrated by the Department of Poultry Science, Bombay Veterinary College, Goregaon East, Mumbai. A function was organized at Goregaon campus of the college. Dr Subodh Naik, Director of Prabhat Poultry Pvt. Ltd., Alibaug was the Chief Guest for the function. Dr Vijay Makhija, General Secretary, INFAH and Dr P G Phalke, Honoray Secretary, CLFMA of India were invited as Guest of Honour. Dr A M Paturkar, Associate Dean, Bombay Veterinary College presided over the programme. Dr P E Avari, conducted the programme.

Dr Vijay Makhija shared the Vision of INFAH of ensuring Healthy Animals & Healthier India to participants. He highlighted the role of Veterinarians in ensuring healthy animals. He presented on the topic of "Egg Marketing – Global Panorma" highlighting the need of marketing initiatives to increase per capita consumption of eggs. Egg being an economical, accessible and having merits of high quality of protein, can address the issue of Malnutrition in our nation. Dr Vijay Makhija gave the prizes of Egg Slogan Competition to winners. In this event, there was great level of collaborative spirit, enthusiasm and active participation.



Dr A M Paturkar, Associate Dean, Bombay Veterinary College appreciated the contribution of INFAH in creating the awareness on nutritional benefits of Egg. He thanked INFAH members for attending the event. Vote of thanks was proposed by Dr D N Desai, incharge, Department of Poultry Science, Bombay Veterinary College.



INFAH HR Subcommittee Meet



The members of HR subcommittee meet at Chennai on 9th October 2017. The event was participated by Dr B P Manjunath, Mr Baskar Varadhan, Mr Devendra Dixit, Dr Joydeep Sarkar, Mr Sudhir Shetty, Mr Umesh Kulkarni,

Mr Vinay Tiwari, and Dr (Capt.) Tanweer Alam.

The agenda of the meeting was to review the activities organised by HR subcommittee, activity chart for subcommittee members, ways to motivate member companies to take the activity, job role presentation and use of digital media.

Key Points:

1. Portal for posting of the opening is becoming successful. Almost 80 CVs have been uploaded. Display in colleges has been done pan India. The discussion has been made in key colleges with the target audience. The activity has increased the awareness about the Animal Health Industry.
2. To streamline the flow of CVs on portal, Job Description will be prepared and uploaded on website.
3. Feed manufacturers and Poultry integrators who are also manufacturing finished feed supplements (even for their own captive consumption) may be included in the reach of the subcommittee.
4. Campus placement needs to attract the students especially from agricultural and management institutes.
5. Information will be collected from INFAH members on the hiring pattern and current need of manpower based on a template that would be circulated among the members which would facilitate hiring from campuses.
6. In order to increase awareness about the animal health industry, an article would be published in print and digital media highlighting opportunities of Animal Health Industry.
7. The subcommittee plans to re-meet in January 2018.

Indian Pharmacopoeia' 2018



The latest Edition of Indian Pharmacopoeia, IP-2018 was released on 29th September, 2017 by Shri C K Mishra, Secretary Health & Family Welfare, Govt. of India in the presence of senior officers of Ministry of Health & Family Welfare and the IP Commission.

The Indian Pharmacopoeia is an authoritative and legally

enforceable book of standard of drugs manufactured / marketed in India. It is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry

of Health & Family Welfare, Government of India in fulfillment of the requirements of the Drugs and Cosmetics Act, 1940 and the Rules there under. It intends to help in the licensing of manufacturing, inspection and distribution of medicines.

Publication of IP on regular basis is an important mandate of IPC aimed at improvement of health of the people and animals through ensuring the quality, safety and efficacy of medicines. The commission has been receiving significant advisory and directions from regulatory authorities and valuable inputs from industrial houses, academic institutions, national laboratories, individual scientists and others. On behalf of the Animal Health industry, INFAH supported the endeavor and worked cohesively with IPC for the IVth Volume of IP' 2018 oriented for animal health formulations, active pharmaceutical ingredients, biologicals and diagnostics. Considering the consistent persuasions of INFAH, IPC has agreed to publish/market the Veterinary volume as part of the



complete set as well alone as desired by the manufacturing units. The Indian Pharmacopoeia (complete set) would be priced at fifty thousand INR while only the Veterinary volume would be available at five thousand INR.

IP-2018 has been brought out in 4 Volumes incorporating 220 new monographs (Chemical Monographs (170), Herbal Monographs (15), Blood and Blood related products (10), Vaccines and Immunoserum for Human use monographs (02), Radiopharmaceutical monographs (03), Biotechnology Derived Therapeutic Products (06), Veterinary monographs (14), 366 revised monographs and 7 omissions.





CLFMA Golden Jubilee Celebration

CLFMA organised the Golden Jubilee Celebration AGM along with the 59th National Symposium on 15th and 16th September 2017 at Mumbai. Celebration was attended by the Central Government minister for Agriculture Shri Radha Mohan Singh and Chief Minister of Maharashtra Mr. Devendra Fadnavis among other dignitaries from the association and industry.



In his inaugural address Shri Radha Mohan Singh emphasized that in order to double the income of farmers by 2022; they should take up livestock farming. He also said that farmers need to enter in fields like horticulture, fisheries, fruit bearing plants, trees and livestock farming, which can easily multiply farmer's income.

The managing committee members of INFAH participated in the event.



Honour to Dr. D K Dey

Dr D K Dey, President, INFAH was felicitated with the "Indian Poultry Review Award" for his long standing contribution towards the Indian Poultry Industry during the Indian Poultry Review Golden Jubilee Celebrations on 24th August' 2017 at Kolkata. Dr D K Dey has significantly contributed towards the Indian poultry biological industry and development of the road map for better biosecurity and diseases control in the poultry sector.



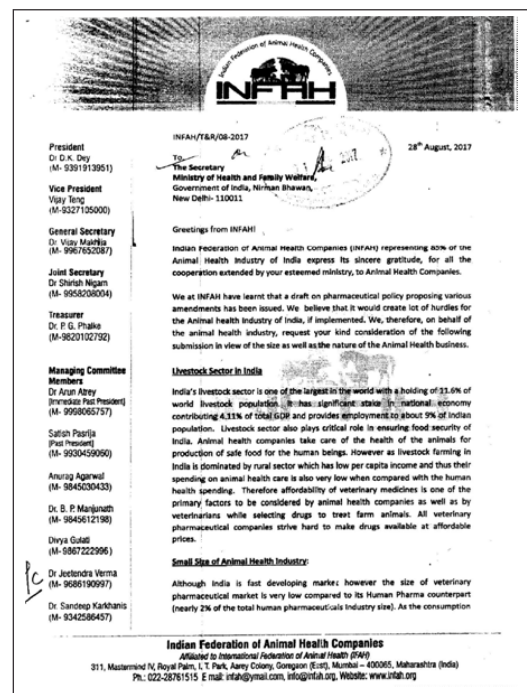
Representation on Draft Pharmaceutical Policy

The Ministry of Health and Family Welfare has released Draft Pharmaceutical Policy 2017. The objectives of the new policy are :

- Making essential drugs accessible at affordable prices to the common masses
- Providing a longer term stable policy environment for the pharmaceutical sector
- Making India sufficiently self-reliant in end to end indigenous drug manufacturing
- Ensuring world class quality of drugs for domestic consumption & exports
- Creating an environment for R&D to produce innovator drugs

Though, primarily the policy has been drafted keeping human pharma industry in focus, there is a possibility of impact on Animal Health Industry too.

As a proactive approach the managing committee has submitted a representation, sharing animal health sectors perspective to Ministry of Health & Family Welfare.



PVS Information Seminar

Four day PVS Information Seminar was organised by DADF on 16th to 19th August' 2017 at National Agricultural Science Centre Complex, Pusa, New Delhi. The seminar was organized to decipher the concept of "Performance of Veterinary Services" (PVS). The concept of PVS evaluation is developed by OIE for its member countries, under which OIE



evaluates the country's infrastructures, policies, manpower and talent; accordingly prepare a report on way forward to make them better aligned with OIE standards.

OIE has 181 countries as members including India. India has been participating in the annual meeting of OIE from last 2 years. So far, 141 member countries have already undergone PVS evaluation; the Government of India has also requested OIE to conduct the PVS evaluation for India. As a first step, this Information Seminar was jointly organised by DADF and OIE to sensitize the key stakeholders of India's livestock sector with the following objectives:

- To convey a solid, general understanding of both the PVS evaluation methods and benefits
- To elicit broad support at all levels for the planning, preparation, conduct and follow up of an OIE PVS evaluation in India.

The event was attended by more than 150 participants, representing top policy makers from all over India at various levels like Principal Secretaries, Directors and Joint Directors of State Animal Husbandry Departments, Vice Chancellors and Deans of Veterinary Universities, Researchers and Academicians from ICAR and Animal Science Research Institutes and stakeholders from other Ministries and Industry.

INFAH participated on day-1 and was represented by Dr Nitin Bhatia. The next three days was attended by the nodal officers of all states, DADF team and OIE team. OIE explained the guidelines to the nodal officers for preparing the state-wise report. The state-wise reports once completed would be submitted at DADF for compilation and preparation of one single report for submission at OIE. The OIE team would also visit few states for validating the data and report. The Secretary, DADF has outlined a time period of 3 months for preparation of national-level evaluation document and another nine months for the states to prepare similar documents.



6th AGM of INFAH held at Mumbai



The 6th Annual General Meeting of INFAH was held on 11th August 2017 at Mumbai. The meeting was attended by close to 100 industry colleagues representing Indian Animal Health and Nutrition Industry.



In the welcome address by Dr. D. K. Dey, Vice President- INFAH, expressed that the role of INFAH has become more significant to meet the new challenges, adopt new culture and practices, be more proactive towards our role in policy making decisions and overall creating new opportunity for sustainable growth by adopting best professional and ethical practices.

INFAH is totally committed to meet the expectations of its members. However, it would need constant encouragement and guidance from all who matter.

Dr. Arun Atrey, President, INFAH congratulated all the members for being a part of INFAH's journey of the last 6 years. Dr. Atrey discussed the vision of INFAH and highlighted various successful representations of INFAH. He also emphasised on the need and role of desired manpower for the industry. Dr. Atrey appreciated the contribution of MC members, SC members and INFAH member companies. He also extended his gratitude towards the support of MOH, MOA, Research Institutes and other associations of the industry.



Mr. Satish Pasrija, Past President & Chairman Sub Committee on Feed Supplements, presented the GST representation in detail. INFAH Members were appraised about entire process of representations done at central, state level and with key stakeholders of GST council.

The AGM proceeded along the well planned agendas.

Agenda: 1: To read & approve Minutes of Meetings of 5th AGM held on 12th August 2016

The minutes of 5th AGM were read by Mr. Vijay Teng, General Secretary, proposed by Dr. Jeetendra Verma, Delacon and seconded by Mr. Divya Gulati, Nurture Aqua.

Agenda: 2: To present & approve the Annual Report of INFAH's activity for the year 2016-17

Mr. Vijay Teng made a comprehensive presentation on the various activities of INFAH undertaken in 2016-17. He also applauded the "Passion" of managing committee and subcommittee members for the untiring and sincere efforts.

Agenda: 3: To present for approval audited balance sheet & income, expenditure accounts together with the Auditors Report

Dr. P. G. Phalke presented the balance sheet & accounts of INFAH. The Auditors Report & Statement of Accounts for the year ended on 31st March 2016 were read, discussed & approved by members.

Agenda: 4: To appoint Auditor to audit the accounts of the Federation during the year 2017-18

The agenda was proposed by Dr. S. K. Karkhanis (Boehringer Ingelheim) and seconded by Mr Deepak Khosla (Ventri Biologicals).

Agenda: 5: To Elect Managing Committee for the period 2017-19

Dr. Phalke announced the New Managing Committee for the Year 2017-19. Dr. D.K.Dey (President), Mr. Vijay Teng (Vice President), Dr. Vijay Makhija (General Secretary), Dr. Shirish

Nigam (Joint Secretary), Dr. P. G. Phalke (Tresurer) and executive members include Dr. Arun Atrey (Immediate Past President), Mr. Satish Pasrija (Past President), Dr. Jeetendra Verma, Dr. B P Manjunath, Mr. Anurag Agrawal, Dr. Sandeep Karkhanis and Mr. Divya Gulati.



At the end there was an open discussion platform for INFAH members in which Dr. Ramdas Kamble (Chembond) shared his thoughts on "Encouraging start ups in Veterinary sector", Mr. Rajesh Aggarwal (Ashish Life Science) shared his thoughts on veterinary products (e.g dewormers) to be sold through OTC route, Dr. Abhishek Garg (Alivira) shared his views on communication of HSN codes to INFAH members post GST regime.



Guest Speaker Presentations

During the AGM Following Insightful presentation were made by Guest Speakers

1) "Corporate Governance, Role & Liabilities of Directors in changing times" presentation made by Mr. Jayesh Udeshi (Company Secretary, Virbac India Private Limited). He



emphasized that becoming a company director has become a very serious business and should not be undertaken lightly or unadvisedly, becoming a company director or already a director, it is very important that one should understand its duties and responsibilities and the potential consequences of their breach.

2) Presentation on "Rural Outreach & Animal Health" was given by Shri. R. S. Sodhi Managing Director, GCMFF (AMUL). He shared rich insights on Indian Dairy Industry, opportunities for Animal Health Industry and major hurdles/road blocks of Dairy Industry. He also emphasized on the slogan of prevention is better than cure. As per Mr. Sodhi, breeding and feeding are the major and valuable inputs of dairy husbandry. His presentation received standing ovation from the delegates.



3) Presentation on "Dynamics of Animal Health Business Strategy in Changed Environment" was deliberated by Mr. Sunil Madhok, Strategy Consultant & Ex. Director of Pfizer India Ltd. He highlighted that India ranks 1st in milk production, 3rd largest in production of poultry eggs and 5th largest in production of poultry meat. Yet, Indian Animal Health Market is 1.6% of Global Market. The gap between being leading dairy & poultry producer vs. the size of the Animal Health market reflects an element of the existing potential to expand the market. He also shared strategy models which can be adopted by the Industry.



INFAH Awards

On the occasion of the 6th AGM, INFAH recognized the contribution of individuals towards development of AH sector in the form of "INFAH Awards".

The INFAH awards were presented to Dr. Vilas Adhikari, Renowned Nutritionist; Shri Ravindra Kumar Agarwal, Founder and Chairman of Natural Remedies; and Shri Sushil Kumar Agrawala, Chairman, Indian Herbs.

Dr. Adhikari has played a major role in the evolution of the Indian Nutrition industry. A former Chairman of PFNDAI (Protein Foods & Nutrition Development Association of India), he is today one of the most sought after speakers on 'Fortification of Foods' at Nutrition Institutes.

Shri Ravindra Kumar Agarwal has been recognized for taking knowledge of Ayurveda across the boundaries, valuing traditional system of medicines and having over three decades of leading expertise in Ayurveda. He is also benefactor to many major charitable institutions across the country.

Shri Sushil Kumar Agrawala has been recognised for his exemplary contribution to society at large and animal health industry in particular. He has been a guiding force to develop and transform Veterinary Ayurveda segment. He is imparting his immense knowledge and wisdom to younger generation as a visiting faculty to many institutions.



All the awardees thanked INFAH for this award and delivered an Inspirational speech by sharing their success mantra with the audience.





Expressions of INFAH Awardees



It is a great privilege and honour to receive the INFAH Award bestowed by the Animal Health Industry. I am greatly thankful to the INFAH managing committee for the memorable recognition. It was a wonderful moment to attend to august event along with the leaders of Animal Health Industry.

The tireless efforts of INFAH managing committee and subcommittee members are praiseworthy. They are leaving no stone unturned for addressing the concerns of Animal Health Industry in India.

I wish INFAH all the success for their endeavour of growth and development of animal healthcare sector.

Regards,

Dr. Vilas Adhikari

I am deeply honoured and extremely thankful for giving me INFAH AWARD-2017 for my contribution to the Herbal Animal Health Sector in our Industry. This recognition motivates me to continue my efforts even though I have crossed 80 years of my life. I once again thank you for honouring me with this award.

I wish to congratulate INFAH & its Members for creating this platform towards the improvement and development of Animal Health Industry at large and Veterinary Ayurvedic Segment in particular.

It is heartening to see the energy with which the past and present Managing Committee of INFAH has been untiringly working towards the industry growth. Your vision and values are very inspiring and I wish you all the best from the deepest of my heart.

Regards

R. K. Agarwal



First of all I wish to thank the Management Committee of Indian Federation of Animal Health Companies for honouring me with the INFAH Award 2017 for my little contribution to the animal health industry, particularly in the Veterinary Ayurvedic segment. I take it as a very unique honour and recognition for my services to the industry.

I must also thank for organizing such a nice AGM and beautiful ceremony for giving away the awards which was memorable and I will cherish it for long. The hospitality and respect extended to me and other directors of our company, Shri Sudhakar Agarwal and Shri Vipul Agrawal, are praiseworthy and commendable. They also join me in extending our gratitude to you. It gives me great encouragement to resolve further to continue to give my best to the Veterinary Ayurvedic Animal Health Industry.

My company, Indian Herbs, has spread its wings beyond the Indian market about 3 decades back and it is now marketing its products in more than 50 countries. It will be our Endeavour to make Indian Herbs a brand recognized in each & every country.

I take this opportunity to greatly appreciate the activities being done by INFAH and wish the INFAH all success to achieve their mission.

With kind regards,

Sushil Agrawala

GLOBAL NEWS

Evidence-based growth standards chart for dogs

Researchers from the University of Liverpool collaborating with University College London, Banfield Pet Hospitals and the WALTHAM Centre for Pet Nutrition have developed the first evidence-based growth standards chart for dogs.

Growth standards for babies and children have become an essential component of the human paediatric tool kit but there was no such standard growth chart available for dogs.

The researchers developing the growth standards chart for dogs had access to the historical health records of over six million dogs visiting Banfield hospitals over the past few years. Statistics experts refined the data until they were left with measurements from 50,000 dogs that met a list of stringent criteria, including being under three years of age, in ideal body condition and with no health complaints. This important step means that the resulting curves represent a "growth standard" for dogs (describing the growth of 'healthy' pets, and intended to represent an ideal), rather than simply a "growth reference".

Instead of classifying growth charts based on breeds, the dog data was classified into five weight ranges and curves were created that followed the growth rate for dogs in those ranges. This size-category approach made the curves suitable for more than just the breeds and also can be used for mixed-breed dogs.

Separate male and female curves for each weight range were created to account for this difference in growth rate of male and female dogs.

Source: <https://www.sciencedaily.com/releases/2017/09/170906114632.htm>

Animal Cancer Foundation receives \$1 million for canine cancer genome project

The Animal Cancer Foundation (ACF), a US based nonprofit organization that supports comparative oncology research that studies the similarities between cancers in people and pets to help find cures for both, has received a \$1 million dollar donation from the Blue Buffalo Foundation.

The grant will provide funding for the Canine Cancer Genome Project (CCGP), which will map the tumor genomes of the most common canine cancers.

Understanding the genetic makeup of canine cancer tumors,

and comparing their genetic makeup to those of people with cancer, will allow researchers to discover additional targeted drug therapies and the least toxic doses of those therapies that are most effective in curing the individual, whether canine or human.

Source: <https://veterinarypracticenews.com/animal-cancer-foundation-receives-donation-canine-cancer-genome-project/>

Pet Insurance Is the Latest Work Perk

Employer-sponsored benefit plans is a fast growing trend in US, under which the family pet are insured against accidents and illness. Some 5,000 companies, including Microsoft, Yahoo, Xerox and Hewlett-Packard, now offer pet insurance, sometimes covering part or all of the costs, in an effort to lure talent but also to recognize the strong emotional bonds between people and pets.

Much like human health insurance, pet insurance comes with a dizzying array of options. A basic plan for certain illnesses and accidents can cost \$20 or less a month; more comprehensive policies covering annual wellness exams, vaccinations, blood work and a range of treatments start at around \$63 a month.

In general, cats tend to cost less to insure than dogs. Many pet insurance companies charge more for breeds prone to certain medical conditions, like cancers or heart disease; a large dog, like a Great Dane, will cost more to insure than a Chihuahua.

Source: <https://www.nytimes.com/2017/06/07/well/family/pet-insurance-is-the-latest-work-perk.html>

Canine Health Week

The Kennel Club, UK's largest organization for pet health and welfare has launched "Canine Health Week" from 13th to 19th November 2017. The week highlighted the most common health issues in the overall dog population and has enabled the owners to familiarise themselves with these in order to establish and meet the healthcare needs of their dogs.

Canine Health Week replaces the previous National Canine Health Testing Week and will be an annual initiative to highlight resources, research and information to help make a difference to dog health by identifying all known health issues rather than just those with an available health test or screening scheme. This will help owners be more aware of and understand the most commonly reported canine disorders that may affect their dogs.

Source: <https://www.thekennelclub.org.uk/press-releases/2017/November/kennel-club-launches-new-canine-health-week/>

NEWS CORNER INDIA

Mr. S P Gupta, the New Chairman of AWBI



Ministry of Environment, Forest and Climate Change has appointed Mr. S P Gupta, an Ex. IAS Officer from Haryana as the new Chairman of Animal Welfare Board of India (AWBI). Mr. S P Gupta is also hailed as the Architect of Gurgaon for his contribution to the development

of the millennium city while working as the chief of Haryana Urban Development Authority (HUDA).

Mr. Gupta has expertise of working in the field of infrastructural development, Housing, Land Acquisition and Agriculture with special emphasis on Organic Farming, Animal Husbandry with special emphasis on Cow Wealth Protection and Samvardhana, Environment & Forest, regulatory and enforcement functions. It was been awarded with many National and International awards. He is founder President of international NGO "People Voice". He has fully devoted himself to the protection of cows and is looking after Kamdhenu Gowdham at Mewat, Haryana.

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Source: Internal

Dr L Ranganath resumes as Dean, Veterinary College, KVAFSU, Hassan



On 29th September' 2017, Dr. L. Ranganath resumed charge as Dean, Veterinary College, Karnataka Veterinary, Animal and Fisheries Sciences University (KVAFSU), Hassan, Karnataka. Prior to the same, he was Professor and Head, Department of Surgery and Radiology,

Veterinary College, KVAFSU, Bengaluru. Prof. Ranganath did his graduation and post graduation in Veterinary Surgery from University of Agricultural Sciences (UAS), Bengaluru and doctorate from Madras Veterinary College, Tamil Nadu Veterinary and Animal Sciences University (TANUVAS), Chennai. He is Fellow of Indian Society of Veterinary Surgery (FISVS) and Indian Society of Advancement of Canine Practice (FISACP). He has guided more than forty postgraduate and five doctorate students and has about 200 research publications to his credit.

Source: Internal

RFID Tags for Dairy Animals

Private and cooperative sector dairies in India are increasingly adopting the latest tagging and tracking technologies to supervise the productivity of individual milking animals and dairy farmers to monitor milk supplies and take corrective steps quickly to suit market demands.

Through the latest technologies of tagging with smart chips of unique identity, these dairies are constantly registering the productivity and health records of individual animals. This helps them predict productivity fluctuations using data analytics and initiate corrective measures wherever intervention is needed, either directly or by advising the dairy farmers. While Amul and Chitale Dairy are among the early adopters of tagging RFID (radio frequency identification) technologies -they have been using these for nearly a decade- Hatsun Agro and Dodla Dairy are among newer ones that have adopted these steps. The company claims the technology helped it increase per capita production several folds.

Source: https://economictimes.indiatimes.com / articleshow /61198319.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

India raises regulatory barrier issues on meat, dairy, pharma with Indonesia

India has raised issues of market access and regulatory barriers with Indonesia that its companies in the pharma, dairy and bovine meat sectors face there. The matter has been taken up by commerce and industry minister Mr. Suresh Prabhu with Indonesia's trade minister Enggartiasto Lukita. The discussion took place as part of the second India-Indonesia Biennial Trade Ministers' Forum Meeting which also agreed to early meeting of Working Groups on Trade & Investment and Trade Facilitation & Remedies. On its part, the Indonesian side agreed to conduct inspection visits for registering dairy products, fresh food of plant origin and meat processing facilities.

Source: https://economictimes.indiatimes.com / articleshow/60833272.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

GADVASU training programme to infuse entrepreneurship in poultry farming

Two week training programme was organised by GADVASU for equipping the entrepreneurial skills on scientific and profitable poultry farming among the educated unemployed youth. The topic of the training was on "Poultry Farming as a Viable Entrepreneurship" and was attended by 54 candidates including students. The candidates were enlightened on various topics like breeds, management, shed design, weather management, vaccination protocols, record keeping, nutritional management, diseases and their prevention, value addition of chicken meat and economics. The practical sessions included handling poultry birds, sign of healthy Vs sick birds, housing design development, beak cutting etc. were also provided to the trainees. To make the trainees practically aware about all aspects, a visit was also arranged to a poultry farm. The trainees hailed the efforts of GADVASU.

Source : <https://timesofindia.indiatimes.com / city />

[ludhiana / gadvasu-training-programme-to-infuse-entrepreneurship-in-poultry-farming / articleshow / 61938994.cms?](https://timesofindia.indiatimes.com / city / ludhiana / gadvasu-training-programme-to-infuse-entrepreneurship-in-poultry-farming / articleshow / 61938994.cms?)

Indore Government Veterinary Hospital gets a Pet Grooming Parlour

The staff at government veterinary hospital in Indore, Snehlataganj is busy grooming pet dogs and cats. The hospital recently started a dog and cat beauty parlour, which is catching attention of pet lovers in the city. The grooming is carried out by two trained employees under the supervision of veterinary doctors. Generally the grooming and parlour services are catered by private operators, it's a new concept in government setup. The 3 packages are offered to the pet lovers depending on the services selected. The various facilities offered are brushing, basic to standing shampoo, blow dry, nail trimming, ear cleaning and deodorant application. The higher packages include sanitary trim, shaving pads, anal gland cleaning, scissoring or chipping work and also anti-tick treatment.

Source: <http://newsdog.today / a / article / 59fd890e12313a00b47d85e2 / ?d=false>

Market Update

Regulatory Framework for Approval of New Animal Drugs in United States

Abstract Animal healthcare is a booming market catering needs of several companion and production purpose animals. Animal drug approval process in the United States (US) involves submission of an Investigational New Animal Drug Application (INAD), followed by submission of New Animal Drug Application (NADA) to the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM). Although regional variations are present in the regulatory process for veterinary healthcare products across the globe, harmonization initiatives like International Cooperation on Harmonization of Technical Requirements for the Registration of

Veterinary Medicinal Products (VICH) are playing a vital role in the veterinary medicinal product registration process by availing detailed guidance documents. The current article focuses on the regulatory requirements for new animal drug registration in the US.

The United States Regulatory Bodies for Animal Healthcare Product Approval

As illustrated in Figure II, regulatory agencies for animal health products approval in the US include the US Food and Drug Administration's (US FDA) Center for Veterinary Medicine (CVM), the US Department of Agriculture's (USDA) Animal and



Figure II: Regulatory bodies for animal healthcare product approval

Plant Health Inspection Service (APHIS) and the Environment Protection Agency (EPA). Whilst the US FDA's CVM reviews animal drugs and devices, the USDA does assessment of animal vaccines and biologics applications, whereas the EPA plays a role in regulating topical compounds against fleas, ticks and other parasites.

The CVM ensures that only high quality, safe and efficacious animal drugs reach the animals and consumers of byproducts. It also safeguards the food items derived from treated animals. CVM's responsibilities are handled by six offices, including the Office of New Animal Drug Evaluation (ONADE), which reviews information submitted by sponsors for obtaining manufacturing and marketing approval for animal drugs, and the Office of Surveillance and Compliance (OSC), which conducts post-marketing monitoring of animal drugs.

Animal Drugs

In US, there is no discrete definition for animal drug. The Federal Food, Drug, and Cosmetic Act (FFDCA) defines the term "drugs" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals" and "articles (other than food) intended to affect the structure or any function of the body of humans or other animals."

In US, the target species for animal drugs are segmented into major and minor categories. Under major species category,

there is a sub-division as companion animals (e.g. dogs, cats, and horses) and food producing animals (e.g. cattle, pigs and chickens). Under minor species, fishes, ferrets, goats as well as all the other animals apart from major species are included. The production animal segment drives almost 59% of the sales with the remainder driven by the companion animal segment [2].

Scientific Assessment of Animal Drugs

Irrespective of variations in regulatory framework across regions, the basic rule of animal drug development includes scientific assessment of animal drug followed by its registration and upon receipt of approval from relevant regulatory bodies, finally marketing of the product.

During scientific assessment, the biopharmaceutical company needs to ensure that adequate information pertaining to safety, efficacy and quality of the test drug has been collected as per the regulatory requirements (Figure III).

Unlike safety assessment of human drugs, veterinary drug safety assessment includes not only patient (animal) safety but also food consumer safety (the drugs targeted for food producing animals).

Besides this handler safety evaluation is required for assessment of safety of the people those will work with animals or have significant contact with animals. In addition to food consumer safety and handler safety the health authorities also require the submission of an Environmental Assessment (EA) or a claim of Categorical Exclusion (CE) for environment safety assessment.

For efficacy assessment, effectiveness of the test drug is tested in the target species, in the targeted disease or the targeted condition.

Quality assessment includes testing for ingredients, manufacturing procedures and facilities, purity and stability of the final formulation, maintaining batch-to-batch consistency in the finished products etc.

New Animal Drug Registration Procedure

Upon conducting market assessment for unmet animal needs, availability of business opportunities and completion of preliminary screening of new drug in the discovery and development stage, if the biopharmaceutical company decides to go for more expensive registration phase, the company needs to submit a letter to the ONADE of CVM to open an Investigational New Animal Drug Application (INAD) file and to initiate the drug registration process. As a part of the development plan, the ONADE and the drug sponsor need to discuss on the information needed to get the drug approved, including the number and types of studies that may be required and the overall design of each study [5]. A clear flowchart of the new animal drug regulatory approval process is illustrated in Figure IV.

The INAD file allows shipment of the drug for use in the studies and may authorize the use of edible tissues from animals treated with the investigational animal drug. Upon establishment of the INAD file, the sponsor plans and conducts



Figure IV: New animal drug development process

the studies needed to support approval. Registration requirements for approval are categorized into seven technical sections, out of which five are major viz., target animal safety, effectiveness, human food safety, chemistry, manufacturing, controls, and environmental assessment, whereas two are minor technical sections viz., product labelling and all other information.

Under the 'target animal safety section', the sponsor submits data on margin of safety study in the target species, tolerability study, reproductive safety study, animal class safety study and other required studies depending on the drug type.

'Effectiveness section' includes data of dose characterization studies/literature and further the field clinical studies, bio-equivalence studies etc.

'Human food safety section' is compulsory for drugs intended for food producing animals only. If the drug product is to be used in a food-producing animal, residues in food products (such as meat, milk, eggs etc.) derived from that animal must be shown to be safe for human consumption. This section includes the toxicology data to determine acceptable daily intake (ADI), residue chemistry data to set tolerance limit and withdrawal time, and microbial food safety data.

For the quality section of the dossier, plans related to 'chemistry, manufacturing and controls (CMC)', for making the drug should be described. It includes data related to details of ingredients and their sources, manufacturing, packaging and storage details, expiry date for test drugs etc.

'Environment assessment (EA) section' is needed under the National Environmental Policy Act (NEPA), wherein the sponsor needs to generate data related to impact of test drug on environment upon its approval. This section describes how much drug is expected to get into the environment and its potential effects on the environment. Specifically applicable for herd/flock treatments, for individual animal treatment e.g. during treatment of pets i.e. dogs and cats, where chances of the drug entering into the environment are rare, the sponsor can apply for waiver off for conducting EA through categorical exclusion application, which indicates that the drug is unlikely to cause a significant environmental impact.

Minor sections i.e. 'product labelling' encompasses labelling information details for immediate container, package insert, outer packaging, shipping label and client information sheet whereas 'all other information section' includes published scientific literature, foreign experience of test drug, medical experience in people and also studies that were conducted by the drug sponsor but not included in the five major technical sections.

During phased application process, once each section is complete, the sponsor submits data to the CVM for review. CVM ensures that the requirements have been met for a particular section, and issues a "technical section complete" letter. CVM also publishes the Freedom of Information (FOI) Summary, which comprises a summary of the safety and effectiveness studies used to support the CVM's decision of animal drug approval. Upon completion of all the technical sections, the sponsor applies for administrative new animal drug application (NADA). The sponsor submits the copies of the technical section complete letters, detailed information on product labeling, and a completed FDA Form 356V (required only for paper based submissions) for an administrative NADA review. Alternatively, the sponsor may submit a single application.

After receipt of all the information, CVM prepares an approval package for the Center Director's signature. If all requirements have been met, the new animal drug application gets approved. An approved NADA means that the drug is safe and effective for its intended use, and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. New animal drug approvals are announced by a Federal Register notice and added to the Code of Federal Regulations and the Green Book.

Guidance Documents

CVM Guidance for Industry provides detailed guidelines for planning, conducting and reporting studies with new animal drugs [6]. Moreover, US being the member of International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH); guidance documents issued by VICH are also primarily used during the development of animal drug candidates [7]. Additionally, applicable human drug guidance from FDA and ICH can also be referred.

Source: Regulatory Framework for Approval of New Animal Drugs in United ... scientific.cloud-journals.com / index.php / IJAVST / article/download/Sci-534/pdf

CALENDAR
Of Events

XXXI Annual Convention of Indian Association of Veterinary Microbiologist, Immunologist and Specialists in Infectious Diseases and National Symposium

29th- 31st January 2018
College of Veterinary Science, SVVU,
Tirupati, Andhra Pradesh

9th Asian Buffalo Congress (ABC- 2018)

1-4th February 2018
Central Institute for Research on Buffaloes, CIRB,
Hissar, Haryana

Indian Veterinary Extension Forum (IVEF) National Conference

29th-31st January 2018
Veterinary College, KVAFSU,
Shivamogga, Karnataka

XVth Annual Convention of Indian Society for Advancement of Canine Practice and International Symposium

7-9th February 2018
NTR College of Veterinary Science, SVVU,
Gannavaram, Andhra Pradesh

36th Annual Convention of Indian Society of Veterinary Medicine and National Symposium

1-3rd February 2018
College of Veterinary Science and Animal Husbandry,
OVAT, Bhubaneswar, Odisha

Indian VETopia

9th-11th February 2018
Kingdom of Dreams, Gurugram, Haryana

XVIIth Biennial Conference of Animal Nutrition Society of India (ANSI)

1-3rd February 2018
College of Veterinary Science and Animal Husbandry,
JAU, Junagadh, Gujarat

18th Indian Veterinary Congress and XXV Annual Conference of IAAVR and National Symposium

23-24th February 2018
College of Veterinary Science, SVVU,
Tirupati, Andhra Pradesh



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