Abiquifi

Informação Regulatória - IFAs e Excipientes

INFOREG - IFA N# 14

NCB Consultoria Farmacêutica

NOVEMBRO de 2016

FDA **U.S. food and drug administration**

1.1 News – Legislação (126/2016)

FDA revisa as suas Diretrizes de Métricas Sobre Qualidade, diz que o Programa será voluntário até 2018, veja mais em:

http://tinyurl.com/j8lk77l (link da RAPS)

1.1 News – Legislação (127/2016)

FDA realizada chamada às empresas farmacêuticas para se juntarem a Programa de Inspeção de Fabricação, veja mais em:

http://tinyurl.com/hn6hhov (link da RAPS)

1.2. Alerta de Importação

1.2.3. Warning Letter (128/2016)

1.2.3.1 Sekisui Medical Co., Ltd. 11/8/16

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm528590.htm

FDA alerta fabricante de IFAs japonesa sobre problemas com integridade de dados, veja mais em:

http://tinyurl.com/zbocp67 (link da RAPS)

Veja as IFAs fabricadas – Aminobutyric Acid / Aminocaproic Acid / Chlorobutanol / Clemastine Fumarate / Gabexate mesilate / Peptide APIs / L- Amino Acids (Leucine, Methionine, Valine) / D- Amino Acids (pharmaceutical intermediate) / Special Amino Acids (pharmaceutical intermediate)

1.2.3. Warning Letter (129/2016)

1.2.3.2 Srikem Laboratories Pvt. Ltd. 11/8/16

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm529237.htm

Veja os IFAs fabricados pela empresa - http://www.srikem.com/products.html

1.2.3. Warning Letter (130/2016)

1.2.3.3 Dongying Tiandong Pharmaceutical Co Ltd 11/10/16

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm530369.htm

FDA alerta fabricante chinesa de **heparina**, reacendendo questões sobre contaminação, veja mais em:

http://tinyurl.com/ztpbuvn (link da RAPS)

1.2.3. Warning Letter (131/2016)

1.2.3.4 CP Pharmaceuticals 11/16/16

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm529931.htm

FDA alerta subsidiária da Wockhardt sobre produção asséptica **(insulina e heparina**), veja mais em:

http://tinyurl.com/zjeoyz9 (link da RAPS)

1.2.3. Warning Letter (132/2016)

1.2.3.5 Beijing Taiyang Pharmaceutical Industry Co Ltd 10/19/16

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm527005.htm

FDA alerta fabricante de medicamentos chinesa por impedir/recusar a inspeção de BPF e manipular dados sistematicamente, veja mais em:

http://tinyurl.com/jhzcz8b (link da RAPS)

Sérias violações de BPF **e obstrução a uma inspeção** / Warning Letter do FDA para um fabricante de IFAs chinês. – ECA Academy

http://tinyurl.com/j4c6dtk (link da Eca Academy)

Veja os IFAs fabricados pela empresa - Allopurinol / Diphenhydramine Hydrochloride / Sodium Aminosalicylate

2. EDQM european directorate for the quality of medicines & healthcare - council of Europe

2.1ews (133/2016

Highlights 156th session of the Ph. Eur. Commission

http://tinyurl.com/hmbvs9h (lin

2.2. Não Cumprimento de BPF

2.3. Suspensão de CEP (134/2016)

Zhejiang Hisun Pharmaceutical Co., Ltd. CN 318 000 Taizhou City 02/11/16

Losartan potassium CEP n#2012-209

https://www.edqm.eu/en/CEP-suspensions-withdrawals-restorations-1536.html

Veja os IFAs fabricados

Anastrozole/ Bicalutamide/ Docetaxel / Actinomycin D / Cyclophosphamide / Methotrexate / Cladribine / Letrozole / Fludarabine phosphate/ Mitomycin / Cytarabine hydrochloride / Epirubicin hydrochloride / Bleomycin hydrochloride Doxorubicin hydrochloride / Granisetron hydrochloride / Daunorubicin hydrochloride / Idarubicin hydrochloride Ansamitocin (AP3) / Bortezomib / Capecitabine / Dasatinib / Decitabine / Epothilone B / Floxuridine / Gefitinib Gemcitabine HCl / Imatinib Mesylate / Irinotecan HCl / Ixabepilone / Mesna / Mitoxantrone HCl / Paclitaxel Pirarubicin / Topotecan / Valrubicin / Vinblastine Sulfate / Vincristine Sulfate / Vinorelbine Tartrate Adenosine / Donepezil HCl / Fluvastatin Sodium / Irbesartan / Losartan Potassium / Mevastatin / Pioglitazone HCl Pitavastatin Calcium / Rosuvastatin Calcium / Valsartan / Atorvastatin calcium / Lovastatin / Pravastatin sodium Simvastatin / Acarbose / Rosiglitazone hydrochloride

Meropenem / Sulbactam / Tazobactam / Tigecycline / Tobramycin / Cilastatin sodium / Imipenem / Amphotercin B Aztreonam + Arginine / Aztreonam / Daptomycin / Demeclocycline / Enoxacin / Micafungin Sodium / Minocycline HCl Moxifloxacin HCl / Nystatin / Tazobactam / Tosufloxacin Tosylate

2.4. Retirada de CEP

3. EMA european medical agency

3.1. News (135 / 2016)

25/11/2016 Insumos Farmacêuticos Ativos: Japão se junta a colaboração intenacional para inspeções GMP, veja mais em: http://tinyurl.com/haqlpdn (link da EMA)

4. MHRA medicines and healthcare products regulatory agency

4.1. News -

5. PMDA pharmaceutical and medical devices agency

5.1. News (136 / 2016)

Encontro de Grupo de Discussão Farmacopéica (PDG) (Outubro 24-26):

PDG is an international discussion group comprised of the representatives of the European Pharmacopoeia (EP), U.S. Pharmacopeial Convention (USP), and Japanese Pharmacopoeia (JP). In this meeting, a new general chapter on Colour (Instrumental method) and a revised general chapter on Amino Acid Determination were signed off. Also, 7 excipient monographs including Hydroxypropylcellulose, Low Substituted were agreed for revision. To date, 30 of the 36 General Chapters and 49 of the 67 excipient monographs on the current work program have been agreed for harmonization. In addition, PDG confirmed that a Stage 4 draft for public enquiry of the "Chromatography" chapter, which is currently on the work program, would be issued in the near future, and that further efforts would be made by the three pharmacopoeias to harmonize "Elemental impurities" text.

Veja mais em: http://tinyurl.com/zung2dy (link PMDA)

6. TGA  therapeutic goods administration

6.1. News

7. CDSCO  central drugs standard control organization

7.1. News

8. CFDA  china food and drug administration

8.1. News

9. ICH international conference on harmonisation

9.1. News (137 / 2016)

30/11/2016 Documento Draft de Perguntas e Respostas do ICH Q11 chega a etapa 2b do Processo do ICH

The ICH Q11 Questions and Answers (Q&As) on the Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities), regarding the selection and justification of starting materials, reached Step 2b of the ICH Process in November 2016 and now enters the consultation period.

Veja mais em: http://tinyurl.com/jkkqbkj (link ICH)

10. PIC/S pharmaceutical inspection convention and pharmaceutical inspection co-operation

10.1. News

11. ECA european compliance academy

11.1. News

12. WHO world health organization

12.1. News (138 / 2016)

24/11/2016 Autoridades Regulatórias Mundiais irão trabalhar para garantir o acesso global a medicamentos com qualidade; Africa está rapidamente progredindo para Agência de Medicamentos Regional, veja mais em:

http://tinyurl.com/h3n62os (link da WHO)

13. USP US Pharmacopeial Convention

13.1. News

14. ARTIGOS ESPECIAIS

Agência de Medicamentos do Vietnã Inclui Aurobindo, Outras Fabricantes de Medicamentos Indianas na Lista Negra

(139 / 2016)

The Drug Administration of Vietnam has added Aurobindo Pharma and five other Indian companies to the blacklist it uses to keep track of drugmakers that violate quality standards. Aurobindo is one of 39 Indian companies on the latest version of the list.

The notice is light on details of what Aurobindo, Brawn Laboratories, Macleods Pharmaceuticals, Prayash Healthcare, Vintanova Pharma and Zee Laboratories did to land themselves on the blacklist. The six Indian drugmakers are joined on the latest batch of new additions to the blacklist by Il Dong Pharmaceuticals of Korea and Nexus Pharma of Pakistan. Indian drugmakers now account for three-quarters of the companies on the blacklist.

That proportion was affected slightly by the companies the regulator removed from the list in the latest update. India's Umedica Laboratories and Zim Laboratories are no longer on the blacklist. Bangladesh's Globe Pharmaceuticals and Korea's Dae Han New Pharm were also removed this week. The regulator also reviewed the cases of three other companies — two Indian, one Korean — but left them on the blacklist.

The update brought no changes to the status of the few Western drugmakers on the list. Vietnamese regulators last provided an update on the status of Apotex, ADH Health Products and Robinson Pharma — the three North American companies on the list — in 2014.

Veja mais em: http://tinyurl.com/jp2vmu6 (link da RAPS)