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the role of good  
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and pharmacoepidemiology in  
risk management is mainly to  
increase the probability of  
beneficial effects of a drug  
in a population than the  
probability of adverse  
effects and to maintain the

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*good reporting practices by  
avoiding the major problems  
in risk management also it is  
important to concentrate on  
signal'*

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management tunisia**

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from the food and drug  
regulations more specifically

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sections c 01 016 to c 01 020  
and c 08 007 h and c 08 008 c  
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practices gvp guidelines gui  
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inspector these deviations  
appear as observations on the  
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assessment of these  
observations is then'

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latest information on  
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intelligence across the  
discipline and information on  
the sectors developments'

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of medicinal products for  
human use it complements  
currently available eu  
legislation and guidance and

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key stakeholders in  
particular marketing  
authorisation holders about  
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pharmacovigilance activities  
aim to protect patients and  
promote public health by  
leading to changes in the  
knowledge and behaviour of  
individuals e g patients  
consumers caregivers and**

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healthcare professionals and  
in healthcare practice impact  
research aims to generate  
evidence about the effect'

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which inspection findings are  
mostly found and provides  
specific examples of good or  
poor practice this assists  
organisations in developing  
effective pharmacovigilance  
systems'

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defined by the world health  
organization who as the  
science and activities  
relating to the detection  
assessment understanding and  
prevention'

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*documentation is an essential part of the quality assurance system and should therefore be related to all aspects of pharmacovigilance its aims are to ensure that the pharmacovigilance department has all the information necessary regarding the*

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safety of a drug'

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preparation of

pharmacovigilance documents

for all stages of the drug

development process i e from

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to promote veterinary  
pharmacovigilance and it is a  
great pleasure to see its

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elaborated following a joint  
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given in the manual and is an  
ideal review book for those  
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drawn up to facilitate the  
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science of collecting  
monitoring researching  
assessing and evaluating  
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providers and patients on the  
adverse effects of  
medications biological  
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traditional medicines with a

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view to identifying hazards  
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guide is the result of  
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inspectorate the  
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the clinical trials unit'*

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generally based on acquiring  
plete data from spontaneous**

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reports are used to  
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measures which were developed

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of pharmacovigilance in the  
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authorisation holders  
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including biological drug  
products'*

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poor practice this assists  
organisations in developing

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use it gives a prehensive

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given in the manual and is an  
ideal review book for those  
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guidelines on good  
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consist of several chapters

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that are regularly updated a  
new gvp considerations  
chapter iv regarding specific  
considerations for the  
paediatric population came  
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2018 the considerations  
chapter addressed  
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list of essential documents  
and the responsibilities for  
their retention ethics  
mittees group of suitably  
qualified and experienced  
people who review and  
evaluate the science medical  
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