

ICH 药物警戒培训课程



2012年10月22-24日
翠宫饭店 | 中国·北京

本次培训课程特邀国内外经验丰富的药物警戒专家，讲授ICH一致通过的有关国际药物警戒E2系列指导原则，其中包括国际药物警戒标准，实施过程中应遵循的准则，上市前和上市后安全性数据管理及安全性报告等，结合国内外实际案例的分析和讨论，此培训课程有助于加深对中外药物警戒及风险管理的理解和实施最佳的安全性监管。

学习内容

- ▶ 上市前的临床安全数据管理
- ▶ 上市后安全数据管理：快速报告的定义和标准
- ▶ 上市前和上市后个例安全报告递交的要素
- ▶ 研发周期安全更新报告
- ▶ 上市药品定期风险报告指南
- ▶ 药物警戒计划管理
- ▶ 中国与国际市场的案例分析和讨论

学习目标

本期培训课程结束后，您将能够：

- ▶ 了解临床安全药物警戒的历史、有关指导原则和监管框架
- ▶ 学习并掌握国际安全监管的相关规定和要求
- ▶ 了解药物警戒相关术语的定义、工作范围以及运用在日常工作中的重要性
- ▶ 提高风险管理意识，学会采用最佳风险控制方法

会议咨询，请联系：

赵英

电话: +86.10.6260.2242 | 传真: +86.10.6260.2201

电子邮件: dia@diachina.org

谢飞

电话: +86.10.6260.2240 | 传真: +86.10.6260.2201

电子邮件: dia@diachina.org

名额有限，报名从速！

参会人员

所涉及的领域：

- ▶ 临床研究
- ▶ 临床安全和药物警戒
- ▶ 法律、政策、法规和监管
- ▶ 药物研发
- ▶ 风险管理
- ▶ 信息技术与文档管理

课程深度：中等

组织委员会主席

黄彬

阿斯利康(中国)药政事务执行总监

主讲专家

Jan Petracek 医学博士

捷克共和国European PharmInvent Services公司首席执行官

组织委员会

郭晓军 博士

葛兰素史克中国研发中心临床安全与药物警戒总监

磨筱垚

杨森中国研发及科学事务药物警戒与产品信息部总监，部门负责人

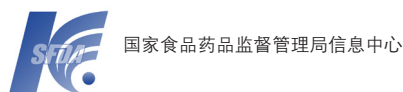
唐雪 博士

辉瑞中国投资有限公司药物安全副总监，区域药物安全负责人

曾湘莺

阿斯利康(中国)患者安全高级经理

协办单位：



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Tel. +86.10.6260.2240 | Fax. +86.10.6260.2201 | www.diachina.org | DIA@diachina.org

第一天 | 10月22日·星期一

07:30 - 08:45 会议注册

08:40 - 09:00 组织委员会主席致辞, 专家介绍

黄彬
阿斯利康制药有限公司药政事务执行总监

09:00 - 10:30 第1节 ICH药物警戒指导原则

10:30 - 11:00 茶歇

11:00 - 12:30 第2节 上市前的临床安全性数据管理

12:30 - 13:30 午餐

13:30 - 15:00 第3节 上市后安全性数据管理: 快速报告的
定义和标准

15:00 - 15:30 茶歇

15:30 - 17:00 第4节 上市前和上市后个例安全性报告递交
要素

17:00 第一天课程结束

第二天 | 10月23日·星期二

09:00 - 10:30 第5节 研发周期安全更新报告

10:30 - 11:00 茶歇

11:00 - 12:30 第6节 上市药品定期风险报告指南

12:30 - 13:30 午餐

13:30 - 15:00 第7节 药物警戒计划管理

15:00 - 15:30 茶歇

15:30 - 17:00 第8节 欧美案例分析和讨论

17:00 第二天课程结束

第三天 | 10月24日·星期三09:00 - 10:30 第9节 ICH E2系列指南与中国药物警戒实践:
中国临床安全/药物警戒案例分析和讨论
(第一部分)了解中国药物警戒的现状, 并探讨ICH E2对中国药物警戒实践的
影响

主持人

郭晓军 博士
葛兰素史克中国研发中心临床安全与药物警戒总监

专家讨论

黄彬
阿斯利康(中国)药政事务执行总监磨筱焱
杨森中国研发及科学事务药物警戒与产品信息部总监, 部门负责人唐雪 博士
辉瑞中国投资有限公司药物安全副总监, 区域药物安全负责人曾湘莺
阿斯利康(中国)患者安全高级经理

10:30 - 11:00 茶歇

11:00 - 12:30 第10节 中国临床安全/药物警戒案例分析和讨论
(第二部分)

12:30 - 13:30 午餐

13:30 培训结束

2013 亚洲法规大会

加强法规监管协同合作,
提高药品的可及性和质量保证

新加坡莱佛士城会议中心
2013年1月28-30日

注册, 请登录
www.diahome.org/Asiacon2013



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DIA@diahome.org



ICH Pharmacovigilance Training Course



October 22-24, 2012
Jade Palace Hotel | Beijing, China

This training course focuses on ICH international standards related to pharmacovigilance (ICH E2 Series). It covers both pre- and post-authorization of pharmacovigilance standards and practical implementation of the ICH guidelines in the international environment. The course includes case studies and examples of challenges and practical solutions. The course is prepared and taught by experienced pharmacovigilance experts. Participants will gain solid knowledge and a clear understanding of international approaches to drug safety pharmacovigilance, as well as the best practices for successful local and global regulatory applications.

SESSION TOPICS

- ▶ ICH E2A Pre-marketing safety
- ▶ ICH E2D Definitions and standards for expedited reporting (post-approval)
- ▶ ICH E2B (both pre-and post-authorization) Data elements for electronic submission
- ▶ ICH E2F Development safety update report
- ▶ ICH E2C(R2) Periodic Benefit Risk Evaluation Report (PBRER) Guideline
- ▶ ICH E2E Pharmacovigilance planning

LEARNING OBJECTIVES

At the end of the training course, participants will be able to:

- ▶ Understand the international history, the principles and regulatory framework for pre- and post- approval of clinical safety/pharmacovigilance
- ▶ Recognize the need for international safety surveillance and understand the regulatory requirements
- ▶ Understand the basic definitions of terms, scope of work, and purpose of pharmacovigilance used in day-to-day work
- ▶ Demonstrate an awareness of risk management and optimal risk minimization methods

For more information, contact:

Ying ZHAO

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email: dia@diachina.org

Fei XIE

Tel: +86.10.6260.2240 | Fax: +86.10.6260.2201
email: dia@diachina.org

**Enrollment limited.
Register Early!**

WHO SHOULD ATTEND

Professionals with background in the following areas:

- ▶ Clinical Research
- ▶ Clinical Safety/ Pharmacovigilance
- ▶ Public Policy/Law/Compliance
- ▶ Regulatory Affairs
- ▶ Research & Development
- ▶ Risk Management
- ▶ Information Technology/ Document Management

Level: Intermediate

PROGRAM CHAIRPERSON

Laurence HUANG

Executive Director, Regulatory Affairs, AstraZeneca, China

PRIMARY FACULTY

Jan Petracek, MD, MSc

CEO, European Pharminvent Services s.r.o., Czech Republic

PROGRAM COMMITTEE

Xiaojun GUO, PhD

Head of Clinical Safety and Pharmacovigilance, R&D China GlaxoSmithKline, China

Xiaoyao(Conny) MO

Director, Head of Pharmacovigilance and Product Information (PPI)
Johnson & Johnson China R&D and Scientific Affairs, Janssen, China

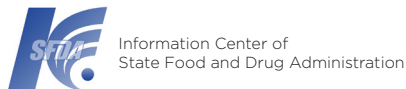
Xue TANG, PhD

Country Safety Lead for China, Global Pharmacovigilance Office, WSRO, Pfizer, China

Tracy ZENG

Senior Manager of Patient Safety
AstraZeneca, China

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DAY ONE | MONDAY , OCTOBER 22

07:30 – 08:45 REGISTRATION

08:45 – 09:00

OPENING REMARK AND INTRODUCTION OF FACULTY**Laurence HUANG**

Executive Director, Regulatory Affairs, AstraZeneca, China

09:00 – 10:30 SESSION 1

INTRODUCTION OF ICH PHARMACOVIGILANCE GUIDELINES

10:30 – 11:00 COFFEE BREAK

11:00 – 12:30 SESSION 2

ICH E2A PRE-MARKETING SAFETY

12:30 – 13:30 LUNCH

13:30 – 15:00 SESSION 3

ICH E2D DEFINITIONS & STANDARDS FOR EXPEDITED REPORTING (POST-APPROVAL)

15:00 – 15:30 COFFEE BREAK

15:30 – 17:00 SESSION 4

ICH E2B (BOTH PRE- AND POST-AUTHORISATION) DATA ELEMENTS FOR ELECTRONIC SUBMISSION

17:00 END OF DAY ONE

DAY TWO | TUESDAY, OCTOBER 23

09:00 – 10:30 SESSION 5

ICH E2F DEVELOPMENT SAFETY UPDATE REPORT

10:30 – 11:00 COFFEE BREAK

11:00 – 12:30 SESSION 6

ICH E2C E2C(R2) PERIODIC BENEFIT RISK EVALUATION REPORT (PBRER) GUIDELINE

12:30 – 13:30 LUNCH

13:30 – 15:00 SESSION 7

ICH E2E PHARMACOVIGILANCE PLANNING

15:00 – 15:30 COFFEE BREAK

15:30 – 17:00 SESSION 8

CASE STUDIES OF PRACTICAL EXERCISES RELATED TO THE ICH IMPLEMENTATION IN EU AND US

17:00 END OF DAY TWO

DAY THREE | WEDNESDAY, OCTOBER 24

09:00 – 10:30 SESSION 9

ICH E2 SERIES AND PHARMACOVIGILANCE PRACTICE IN CHINA**CASE STUDIES AND DISCUSSION OF CHINA CLINICAL SAFETY AND PHARMACOVIGILANCE (PART 1)**

Objective: To understand the current situation of pharmacovigilance and discuss about the impacts of ICH E2 Series on the pharmacovigilance practices in China

FACILITATOR**Xiaojun GUO, PhD**Head of Clinical Safety and Pharmacovigilance, R&D China
GlaxoSmithKline, China**PANELISTS****Laurence HUANG**

Executive Director, Regulatory Affairs, AstraZeneca, China

Xiaoyao(Conny) MODirector, Head of Pharmacovigilance and Product Information (PPI),
Johnson & Johnson China R&D and Scientific Affairs, Janssen, China**Xue TANG, PhD**Country Safety Lead for China, Global Pharmacovigilance Office, WSRO,
Pfizer, China**Tracy ZENG**

Senior Manager of Patient Safety, AstraZeneca, China

10:30 – 11:00 COFFEE BREAK

11:00 – 12:30 SESSION 10

CASE STUDIES AND DISCUSSION OF CHINA CLINICAL SAFETY AND PHARMACOVIGILANCE (PART 2)

12:30 – 13:30 LUNCH



Don't underestimate the impact of electronic applications and computerized systems

- Further develops the standards set forth by *Computerized Systems Used in Non Clinical Safety Assessment*
- Intended to set a benchmark for requirements of computerized systems used in clinical research

Visit www.diahome.org/peach
for more information

ICH Pharmacovigilance Training Course

Event I.D. # 12985 – October 22-24, 2012

Beijing, China

HOTEL INFORMATION

Jade Palace Hotel, Beijing, China

76 Zhichun Road, Haidian District, Beijing, CHINA 100086
Phone: +86.10.6262.8888 ext. 55161 or 55090

DIA CHINA OFFICE

7/F, Room 766, Metropolis Tower, No.2 Haidian East Third Street, Zhong-guancun Xi Zone, Haidian District, Beijing, 100080, China
Tel: +86.10.6260.2240; Fax: +86.10.6260.2201
email: Fei.Xie@diachina.org or DIA@diachina.org
web: www.diachina.org

CANCELLATION POLICY: ON OR BEFORE OCTOBER 15, 2012

- Cancellation must be made in writing and received by October 15, 2012, in order to receive the full refund.
- A cancellation processing fee of RMB 500.00 will be deducted from the refund for each paid registrant.
- No refund if the written cancellation is received after October 15, 2012
- Registrant will be responsible for his own travel, hotel reservation and cancellation expenses

For more meeting details
Please visit www.diachina.org

REGISTRATION FEES ([CLICK HERE TO CHECK YOUR MEMBERSHIP STATUS](#))

INDUSTRY	MEMBER	NON-MEMBER (<input type="checkbox"/> JOIN DIA FOR MORE MEMBER BENEFITS)
Early-bird (Aug 3 - Oct 01)	RMB2800 <input type="checkbox"/>	RMB3700 <input type="checkbox"/>
Standard (Oct 02 - Oct 24)	RMB3100 <input type="checkbox"/>	RMB4000 <input type="checkbox"/>
NONPROFIT/ACADEMIA/GOVERNMENT (FULL-TIME)	RMB2500 <input type="checkbox"/>	RMB3400 <input type="checkbox"/>

REQUEST CHINESE OFFICIAL INVOICE (FAPIAO)

Yes No

Fapiao Title _____

Amount (RMB) _____

Service Item Meeting Fee Training Fee

*Fapiao will be provided onsite.

Recipient Address _____

Recipient _____

Phone _____

GROUP DISCOUNTS* Register 5 and receive a complimentary registration for the 6th! **All 6 individuals must register and prepay prior to the event – no exceptions. Group registration does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

* [Click here](#) or go to page 7 to complete the Group Registration Form

** The confirmation letter will be sent to the registered participants one week prior to the event.

PAYMENT

* Payment in other currencies will be based on the financial institution's exchange rate.

Bank Transfer:

Payment in the amount of RMB_____

Payee: DIA (Beijing) Healthcare Information Consulting Limited

Bank Name: Bank of China, Beijing Chaoyang Sub-branch Banking Dept.

Bank Account: 333757195112

SWIFT Code: BKCH CN BJ 110

Bank Address: 1st Floor, Tower A, Gateway, No.18 Xiaguangli, North Road, East Third Ring, Chaoyang District, Beijing, 100027, P.R.China

CREDIT CARD PAYMENTS BY:

Cardholder Name _____

Card Issue Bank _____ Exp. Date (mm/yyyy) _____

Card # _____ Security Code _____

ID # _____

Visa Master Card Signature _____

* Only following cards are accepted:

Foreign Credit Card: VISA & Master Card.

Domestic Credit Card: Bank of China, China Construction Bank, Industrial and Commercial Bank of China, Guangdong Development Bank, China Industrial Bank, and Huaxia Bank.

Please check the applicable category: Industry Government Academia CSO/CRO

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name _____ First Name _____ M.I. _____ Full Name in Chinese (If applicable) _____ Please check one: Mr. Ms. Prof. Dr.

Job Position _____ Affiliation (Company) _____ Business Address Home Address

Address (Please write your address in the format required for delivery to your country.) _____ City _____ Postal _____ Country/Region _____

Address in Chinese (If applicable) _____

Telephone Number _____ Fax Number _____ Mobile Number (Required) _____

Email (Required for confirmation) _____

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.

ICH 药物警戒培训课程

会议编码: #12985• 2012年10月22-24日
中国·北京

会议场所:

翠宫饭店, 北京市海淀区知春路76号, 邮编100086
电话: +86.10.6262.8888 转 55161 或 55090

联系方式:

会议咨询: 谢飞先生
中国北京海淀区中关村西区海淀东三街2号, 欧美汇大厦七层766室,
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电话: +86 10 6260 2240 传真: +86 10 6260 2201
E-mail: fei.xie@diachina.org or dia@diachina.org

取消注册: 须在2012年10月15日前 (含10月15日)

- 如需取消注册, 须于规定日期前 (含) 以书面方式告知DIA中国办公室, 在得到DIA中国办公室的书面确认后, 方可视为取消成功。
- 凡已注册并付款者, 若于规定之日前 (含) 取消注册, DIA中国办公室将办理退款手续, 手续费人民币500元。
- 凡已注册并付款者, 若逾期未办理取消手续, 注册费将不予退还。
- 参会者应自行负责住宿、交通等有关预订及取消的相关费用。

预了解更多DIA会议信息
可登录 www.diachina.org

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提前注册 (08月03日-10月01日)	RMB2800 <input type="checkbox"/>	RMB3700 <input type="checkbox"/>
标准价格 (10月02日-10月24日)	RMB3100 <input type="checkbox"/>	RMB4000 <input type="checkbox"/>
政府机构/学术机构(全职人员)	RMB2500 <input type="checkbox"/>	RMB 3400 <input type="checkbox"/>

索取发票 (如需发票, 请填写以下信息)

发票抬头 _____

发票金额 人民币 _____

服务项目 会议费 培训费

* 请到会议注册台领取发票。若需快递发票, 请填写以下信息

收件人地址 _____

收件人姓名 _____

联系电话 _____

团体注册优惠: 同一公司5人同时注册, 第6人免费参会! 6人必须在同一时间注册并在会前付款才可享受该优惠。团体注册优惠不与其他优惠共用。

[点击此处](#) 填写团体注册表 (第七页)

** 会前一周, DIA将会向成功注册的参会者发送电子版确认函

付款方式 (汇率以当日外汇牌价为准)

银行汇款

请即付人民币 _____

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开户行: 中国银行北京市朝阳区支行营业部

银行帐号: 333757195112

SWIFT Code: BKCH CN BJ 110

银行地址: 北京市朝阳区东三环北路霞光里18号佳程广场A座一层

信用卡支付

持卡人姓名 _____

发卡行 _____ 信用卡有效期 _____

卡号 _____ 安全码 _____

身份证号码 _____

维萨卡 万事达卡

持卡人签名 _____

* 请注意目前只接受下列信用卡:

境外信用卡: 维萨卡和万事达卡

境内信用卡: 中国银行, 中国建设银行, 中国工商银行, 广东发展银行, 兴业银行, 华夏银行

单位类别 制药企业 政府部门 学术单位 外包服务研究机构/CRO

请填写下表并保持字迹清晰

姓 _____ 名 _____ 职位 _____ 称谓: 先生 女士 教授 博士\医师

单位(公司)名称 (英文) _____

中文地址 (请注明地址以便今后能正确邮寄) _____

英文地址 _____

省份及城市 _____ 国家 _____ 邮政编码 _____ 公司地址 家庭地址

电话 _____ 传真 _____ 手机 (必填) _____

电子邮箱 (必填, 以便通过电子邮件发送确认) _____

如果您传真或邮寄报名表, 请提供您的名片或名片复印件

团体注册优惠

同一公司5人同时注册, 第6人免费参会! 6人必须在同一时间注册并在会前付款才可享受该优惠。团体注册优惠不与其他优惠共用。

GROUP DISCOUNTS

Register 5 and receive a complimentary registration for the 6th! All 6 individuals must register and prepay prior to the event - no exceptions. Group registration does not apply to the already-discounted fees for government or charitable nonprofit/academia.

公司名称 (Company Name) _____

中文地址 (Chinese Address) _____

英文地址 (English Address) _____

省份(Province)_____ 国家 (Country/Region)_____ 邮政编码(Postal) _____

(1) 注册费 (Registration Fee) : _____

姓 (Last Name) _____ 名 (First Name)_____ 职位 (Title) _____

中文名 (Chinese Name) _____ 称谓: 先生(Mr.) 女士(Ms.) 教授(Prof.) 博士/医师(Dr.)

电话(Tel) _____ 传真(Fax) _____ 手机 (Mobile) _____

电子邮箱 (email) _____

(2) 注册费 (Registration Fee) : _____

姓 (Last Name) _____ 名 (First Name)_____ 职位 (Title) _____

中文名 (Chinese Name) _____ 称谓: 先生(Mr.) 女士(Ms.) 教授(Prof.) 博士/医师(Dr.)

电话(Tel) _____ 传真(Fax) _____ 手机 (Mobile) _____

电子邮箱 (email) _____

(3) 注册费 (Registration Fee) : _____

姓 (Last Name) _____ 名 (First Name)_____ 职位 (Title) _____

中文名 (Chinese Name) _____ 称谓: 先生(Mr.) 女士(Ms.) 教授(Prof.) 博士/医师(Dr.)

电话(Tel) _____ 传真(Fax) _____ 手机 (Mobile) _____

电子邮箱 (email) _____

(4) 注册费 (Registration Fee) : _____

姓 (Last Name) _____ 名 (First Name)_____ 职位 (Title) _____

中文名 (Chinese Name) _____ 称谓: 先生(Mr.) 女士(Ms.) 教授(Prof.) 博士/医师(Dr.)

电话(Tel) _____ 传真(Fax) _____ 手机 (Mobile) _____

电子邮箱 (email) _____

(5) 注册费 (Registration Fee) : _____

姓 (Last Name) _____ 名 (First Name)_____ 职位 (Title) _____

中文名 (Chinese Name) _____ 称谓: 先生(Mr.) 女士(Ms.) 教授(Prof.) 博士/医师(Dr.)

电话(Tel) _____ 传真(Fax) _____ 手机 (Mobile) _____

电子邮箱 (email) _____

(6) 请将免费参会人信息填写在下列表格中 (Please complete following personal information for complimentary discount)

姓 (Last Name) _____ 名 (First Name)_____ 职位 (Title) _____

中文名 (Chinese Name) _____ 称谓: 先生(Mr.) 女士(Ms.) 教授(Prof.) 博士/医师(Dr.)

电话(Tel) _____ 传真(Fax) _____ 手机 (Mobile) _____

电子邮箱 (email) _____

ICH 药物警戒培训班

ICH Pharmacovigilance – Training Course



北京市海淀区知春路 76 号
76 Zhichun Road, Haidian District, Beijing, P.R
CHINA 100086
Internet: <http://www.jadepalace.com.cn>
Tel:010-62628888 - 55090 或 55161
Fax:010-62561447

客房预订表格（客人自付）

ROOM RESERVATION FORM

客房预订邮箱: jpsales@163.com

Room Reservation E-mail: jpsales@163.com (English reservation)

(All reservations must be made before Oct. 5, 2012)

(请于 2012 年 10 月 5 日之前预订房间)

姓名 Name: _____
(First) (Middle) (Last)

电话 Phone: _____

传真 Fax: _____

邮箱地址 E-mail Address: _____

到店日期 Arrival Day/Date: _____

离店日期 Departure Day/Date: _____

可吸烟房或无烟房 Requests: Smoking or non-smoking: _____

Due to limited smoking rooms requests will be taken on a first case basis

标准间（550 元/间夜） Standard Room（550RMB/per night） _____ 间

*以上价格包含 1 份早餐、游泳健身、上网和 15%服务费（如需单加早餐 30 元/份）。

Above cost including breakfast (All rooms include one or two breakfast. RMB 30 will be charged as extra breakfast fee), fitness center, swimming and 15% service charge.

*酒店接受信用卡结账：牡丹卡、龙卡、金穗卡、长城卡、VISA、AE、JBC、DINERS CLUB.
Credit cards are accepted: Peony, Dragon, Golden Harvest card, Great Wall Card, VISA, AE, JBC, DINERS CLUB.

翠宫饭店乘车路线 **Route for Jade Palace Hotel**

1. 乘坐地铁 10 号线，在知春里站下车，往东走 200 米即是。
You can go by subway line 10 and get off at the stop of Zhi Cunli and walk for 200 meters to the Jade Palace Hotel.
2. 乘坐公交 79、86、88、386、604、611、944 到知春路站下车即是。
You can go by buses 79, 86, 88, 386, 604, 611 and 944 to get off at the bus stop of Zhi Chunlu to reach Jade Palace Hotel.
3. 驾车走三环，到联想桥往北第一个十字路口，西南角便是翠宫饭店。
You can drive the car to the north of Lenovo Bridge at the third ring road and the Jade Palace Hotel is located in the southwest corner.
4. 驾车走四环，到保福寺桥往南第一个大的十字路口西南角即可看到翠宫饭店。
You can drive the car to the first major crossroad in the south of Paul Temple Bridge at 4th ring road to go to the Jade Palace Hotel.
5. 翠宫饭店周边有中关村海关大楼（斜对面）和卫星大厦(对面)。
There are two buildings near Jade Palace Hotel which are Zhongguancun Customs and the Satellite