

## GCI TECH NOTES©

### GCI 的工艺摘要

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## 分析化实验室的设计和发展

### Analytical Laboratory Design and Development

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Gossman Consulting, Inc. (GCI) personnel have been designing and developing analytical laboratories for more than 18 years. From the beginning the emphasis has always been on determining the most practical and needs-oriented designs for the company or client for whom the designs have been done. Many factors go into the mix of design and development work. This Tech Notes will provide some brief guidelines that are important to the laboratory design and suggest areas that should be high priorities in the development phase.

The first step in the design process is to understand the purpose of the laboratory. A laboratory designed for typical commercial analysis of samples can be far different from a laboratory designed for meeting the needs of a process quality control lab, or an analytical research laboratory. All conduct analysis and may use some of the same instrumentation but it is at this very basic point that they begin to differ in purpose and, therefore, also need to differ in design.

高士曼咨询有限公司(GCI)人员在18年中曾经设计和发展过很多分析化实验室。从开头就注重公司或客户的实际需要,然后才为他们进行设计。许多因素把设计和发展的工作混合起来。在这份工艺摘要中,我们提供一些对化实验室的设计颇为重要的扼要准则,并且建议有些方面在发展的阶段中应当极度优先[考虑]。

设计过程的第一个步骤就是了解化实验室的用途。设计一个典型的作商业样品分析用的化实验室、与设计一个符合过程质量控制需要的化实验室、或者是一个分析研究用的化实验室的分别可能大相径庭。所进行的分析也许用一些同样的仪器,但是从最基本的观点出发他们的用途开始有所分别,因此对设计的要求也不同。

The purpose of the commercial lab is to be a profit center unto itself. It does not create a product to sell per se, other than the analytical results that they produce for each sample they receive. Therefore, the numbers of samples worked on, along with the quality of the analytical results as normally directed by a regulatory frame-work, are of paramount importance to the typical commercial laboratory. Thus economies of scale must be realized and integrated into the design of such a laboratory.

The process quality control lab may use some of the same instrumentation as the commercial lab. However, the analytical information obtained is not an end product as in a commercial lab, but rather assistance and support in process quality control decision making. The analyst usually has other information and uses the lab analysis to confirm or support a process decision. Processes are normally continuous or on-going, thus turnaround time of the analysis, along with quality of the analytical results as directed by the process parameters, are of critical importance to a typical process quality control laboratory.

A research lab differs in purpose from both of the previous two examples even though it may use some of the same instruments. The purpose is to originate or improve analytical methods or products. Neither sample number nor turnaround time is an immediately critical factor to the design. The designs should provide for flexible lab space to setup and change experiments, to run parallel testing, and to provide access to large and varied reference materials. It also needs to provide for quality controls which may vary according to the stage of research, yet support reproducibility. Clearly the purpose has a major influence on the design of a laboratory.

Most of the laboratories that GCI has designed and/or developed have been a combination of the process quality control and commercial laboratory purpose. The laboratory designs were often based more on process quality control but because of regulatory analysis requirements and the number of samples coming into the labs, the designs contained features that follow a design for a commercial laboratory.

商业用化实验室的用途是以赚取利润为核心. 它本身并不创造产品出售, 只是为收到的样品进行分析和提供分析的结果. 因此, 工作的样品数目与质量分析的结果通常是按规定的框架, 那就是一般商业用化实验室的最重要的职责. 因此提高效率必须在设计这类化实验室时考虑进去。

过程质量控制用的化实验室也许所用的仪器, 有些是与商业化实验室相同的仪器. 不过, 分析所得的资料, 并非如商业化实验室那样, 为最终的产品, 而是帮助和支持在过程质量控制中的决策. 分析员通常还有其他资料, 用化实验室的分析来确定, 或支持对一个过程的判决. 过程经常是连续的或持久的, 因此分析的返回时间, 与分析结果的质量受过程的周边数据来进行, 对一个过程质量控制用的化实验室是非常重要的。

在用途上一个研究用的化实验室与上述的另外两个例子有分别, 就算用的是一些同样的仪器. 它的用途是追寻或改良分析的方法或产品. 无论样品的数量或返回时间对设计来说都不是一个即时重要的因素. 设计上应该给与化实验室灵活的空间来进行和改变试验、进行平行的测试和提供方便以取得大量和不同的参考资料. 它还需要按照研究的阶段提供质量控制, 此外还要支持再现性. 很明显用途对设计一个化实验室有相当大的影响。

大部分 GCI 曾经设计过的, 或者发展出的化实验室, 已经融合了过程质量控制和商业化实验室的用途. 化实验室的设计经常是多些倾向于过程质量控制, 但是因为法定的分析要求, 和送来的样品数目, 于设计方面含有一些特色是沿用一种商业化实验室的设计。

To examine the design and development, a checklist of items that GCI has used can be drafted which provides an oversight to this process. This checklist is generic in its content because each individual project would require a specific list based on the scope of activities to be performed by the laboratory.

为了检验设计和发展，GCI 拟就一个核对用的细目清单提供对这个[检验]程序的监督。这个清单是一般性的内容，因为每一个项目会需要一个特别的清单，根据化验室要进行的活动范围。

#1 Of course the first item is defining the purpose of the laboratory. The need for this is briefly elaborated above. The following are key points in this item:

#1 当然第一项是明确化验室的用途。需要这样做的原因在上面已经简略地解说过。以下是每项的关键点：

- 商业用化验室 Commercial laboratory
- 过程质量控制[化验室] Process quality control
- 研究用化验室 Research laboratory
- 恰当的分析方法 Appropriate analytical methods
- 书面分析计划 Written analysis plans
- 书面的标准操作程序 Written Standard Operating Procedures (SOPs)

#2 The physical location of laboratory is an early important item. Is the laboratory going to be attached to or modified from an existing facility? Will it be located on an existing facility, a partner facility or on a separate site?

#2 化验室的实际位置是初步重要的一项。化验室是否要附设于，或由一个现有的设施改装过来？它是否需要设置于一个现有的设施之内、一个关联的设施内、或者是在另外一个地点？

- 改装现有的化验室 Modify existing laboratory
- 改装现有的大厦 Modify existing building
- 附设于现有的化验室 Attached to existing laboratory
- 附设于现有的大厦 Attached to existing building
- 设于现有设施的现场 On-Site at existing facility
- 设于关联设施的现场 On-Site at partner facility
- 对关联设施的远程支援 Off-Site support of partner
- 另外设于商业地点 Separate commercial site

#3 Examining and determining the needs and use of analysis information was probably started with #1 while deciding on the purpose of the laboratory. Item #3 of the design/development process will describe some items that must be accounted for in providing for efficient flow of sample analysis and results. It would be normal for a lab analyzing for process quality control information to need to communicate some results to the decision-maker immediately or within minutes. In order to accomplish this, the sample prep area and key analytical instruments and equipment must be located close by and in efficient order. The analysis may require several different analytical steps to be performed to obtain the quick turn-around information needed.

A commercial or research lab would not normally have this requirement. The commercial lab would more likely need to departmentalize the sample prep and various analysis areas so that economies of scale can be achieved while analyzing many samples at once. The research lab has need of neither arrangement but is clearly served by good organization of similar analytical instrument type. As an example of designing for specific needs, a checklist of items for a process quality control lab would have consideration for at least the key following points:

- 准备样品的的位置 Sample prep area location
- 仪器的排列 Arrangement of instrumentation
- 分析人员的流程 Flow of analytical personnel
- 化验室的文书工作的位置 Arrange lab paperwork areas
- 与决策者的联系 Communicate to decision-maker
- 标准操作程序的计时 Time-study based SOPs

The above points to be considered are supported by some additional more detailed considerations for the actual physical plant of the laboratory, such as:

#3 使用上面 #1 项的分析资料, 来检查和确定化验室的需要作为开始, 同时决定化验室的用途. #3 项的设计和发展程序, 会描述出一些目录, 必须考虑到提供高效率的样品流程和其测试结果. 在正常情况下, 一个化验室作程序质量控制资料, 会有需要马上或在几分钟之内, 把有些测试结果通知决策者. 为了达到这个要求, 准备样品的地方和关键的仪器和设备必须设置在就近位置, 按高效率地排列. 分析的工作也许有要求做几个不同的分析步骤来进行, 以获得需要的快速资料反馈。

一个商业用或者研究用的化验室通常不会有这个要求. 一个商业用的化验室, 大致上会有需要把准备样品的工作, 和不同的分析领域, 分别由不同的部门负责, 这样做可以实现高效率同时分析许多样品. 研究用的化验室不需要上述的安排, 但是清楚地使用相同的分析仪器类型构成一个良好的组合. 作为设计特殊需要的[化验室]的一个例子, 应该有一个给过程质量控制用的化验室作核对用的清单, 至少有下列关键点需要考虑:

以上几点被认为是支持其他一些额外的、更仔细的考虑, 为一个真实的工厂化验室所需要的, 例如:

- 线路和电力出口[插头]的数目与位置 Number and location of electrical outlets/circuits
- 室内供热、通风、空调系统【注 1】必须恰当地平衡，并非通风橱或排气管  
HVAC system must be balanced properly vs. fume hoods/exhausts
- 最恰当的柜台高度及宽度 Counter optimum heights/depths
- 有些地方可以用比较便宜的储藏柜或陈列柜 Less expensive cabinets can be used in some areas
- 通风橱的空间与旁通管道【注 2】 Fume hood space and bypasses
- 分析用供气的位置 Location of analytical gas supply
- 样品储存库与工作地方 Sample storage vs. work area
- 样品储存库需符合法规防止污染和危险 Sample storage to meet code & prevent contamination & hazards
- 防爆冷冻箱（库） Explosion-proof refrigeration
- 紧急逃生门的数目和位置 Number and location of emergency egress doors
- 洗眼药水、安全淋浴室、个人防护装备市规定的也是应该有的 Eyewashes, safety showers, PPE as required and preferred
- 语音和通讯设备 Voice and telecommunications
- 试剂储存库须符合法规要求，防止污染和危险 Reagent storage to meet code and prevent contamination or hazards
- 员工们休息、午餐地方和储物柜 Employee break/lunch/lockers
- 行政、排期、化验室的管理，文件和资料记录的保管 Administrative, scheduling, lab management, documentation and records retention
- 扩张化验室的空间 Expansion of lab space

Some of these items are decided by ergonomics, some are economics, some are safety but how each one is configured into the design is critical to achieving efficient operations in the process quality control laboratory.

以上有些细目是由工作环境改造来决定、有些是由经济因素来决定、有些是基于安全考虑，但是每个细目配备于设计中都是为了达到过程质量控制化验室的高效率运作。

#4 This key item may seem to have less to do with the design of the physical plant of the laboratory than the actual operation. However, serious consideration should be made to lab staffing, not just staff numbers but also their functions. Some administrative functions require more space and electronic support than the actual lab. The following are key points for this item:

- 工作记述 [Job descriptions](#)
- 个人资历 [Personnel qualifications](#)
- 职位的数目 [Number of positions](#)
- 人员的培训 [Training of personnel](#)

A good lab design will support the efforts of the lab staff in meeting analytical and economic goals and yet accommodate some flexibility. Practical work experience in labs of various designs with all of these issues and lab design experience will lead to a superior design. GCI recommends that if you are seeking to redesign your lab or design a new lab, that your design takes into critical review most, if not all, of these items.

#4 关键的一项似乎与设计化验室所属的真实厂子的实际运作没多大关系。但是,在招聘化验室的工作人员方面应该认真考虑,并非仅仅是员工的数目而是他们能起的作用。有些行政方面职责需要多些空间和电子支援多于在化验室现场。以下是这个细目的关键点:

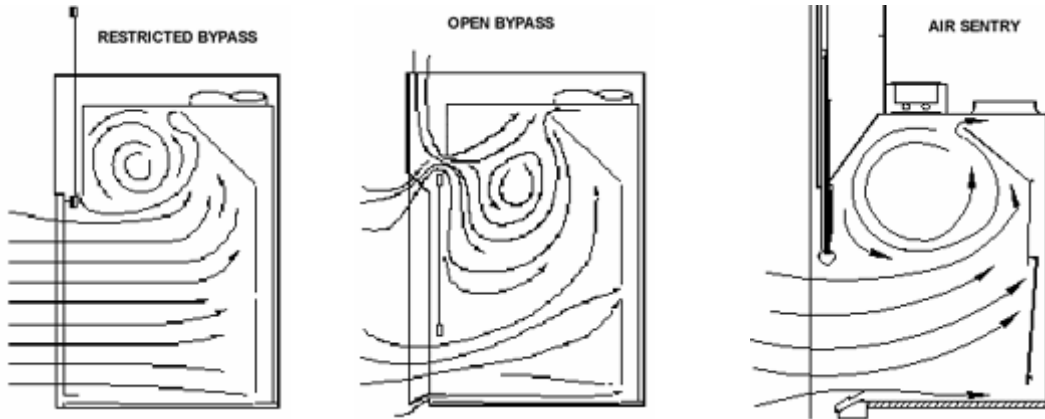
一个好的化验室设计会支持化验室的员工的工作,以符合分析和经济的目标,而且也容纳一些灵活性。在不同的化验室设计有实际的工作经验,对付上述的那些问题,会设计出优秀的化验室。GCI建议如果你们正在考虑重新设计你们的化验室,或者设计一个新的化验室,那你们应该严肃对待你们化验室的设计,如果不是全部,至少上述的有些细目值得考虑。

【注1】H = Heating (供暖气), V = Ventilating (通风), AC = Air-Conditioning (空调) HVAC就是指室内的暖气、通风和空调的设施。有时被称作“气候控制”[也有说是“恒温控制”]那是设计中型至大型的工业和办公大楼时特别重要,如摩天大厦和水属馆,那里的湿度与温度必须是有紧密的关联,以保持室内的安全和健康。按英国的 [Wikipedia 免费百科全书的解说](#)。

**HVAC** (pronounced either "H-V-A-C" or, occasionally, "H-VAK") is an [initialism/acronym](#) that stands for "**heating, ventilating, and air conditioning**". This is sometimes referred to as "climate control" and is particularly important in the design of medium to large industrial and office buildings such as [sky scrapers](#) and in marine environments such as [aquariums](#), where humidity and temperature must all be closely regulated whilst maintaining [safe and healthy](#) conditions within. [From Wikipedia, the free encyclopedia](#)

【注2】Fume hood space and bypasses 化验室用通风橱的空间与旁通管道

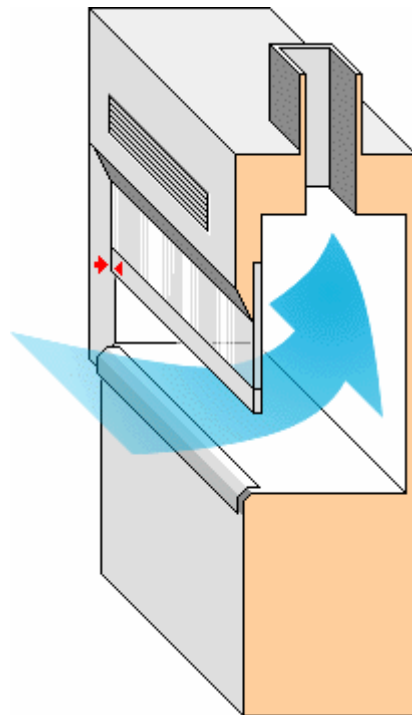
见下图 ...



Restricted Bypass Fume Hood

Open Bypass

Air Sentry



### That is how a fume hood looks like

欲作更多咨询，或者你有什么经验可以与我們分享，請联系 Mr. David Gossman, 电话 001-847-683-4188, 或者发电邮 [dgossman@gcisloutions.com](mailto:dgossman@gcisloutions.com) 中国的朋友们可发电邮给我公司驻中国代表— 张启明先生 <dennis.june@gcisolutions.com>

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